Intense Sweeteners and Preservatives: Contemporary Regulation and Historical Baseline Data of the Nature and Amounts in Soft Drinks on open sale in Northern Ireland

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Summary

Food additives consistently attract consumer interest and some concern despite the existence of strict regulation. This paper describes the current regulation of intense sweeteners and preservatives in Northern Ireland. The authors have also collated previously unpublished survey data from 1999 and 2004 thus placing baseline information in the public domain on the nature and the amounts of intense sweeteners and preservatives in soft drinks on open sale in Northern Ireland at those times.

The 1999 survey covered ice cream and meat products which were analysed for colours and soft drinks which were analysed for intense sweeteners. The latter aspect is reported here. Of 35 soft drinks 15 samples (42.9%) failed to meet legal requirements; 11 (31.4%) for defective or misleading labels, 3 (8.6%) because of excess saccharin and in one case (2.8%) failure to declare the presence of saccharin and aspartame.

Similar findings were also a feature of the 2004 survey when 121 samples of various, mainly soft drinks were analysed for intense sweeteners and preservatives where18 samples (14.9%) failed to meet legal requirements. Defective or misleading labels accounted for 10 (8.3%) failures, 3 (2.5%) had excess saccharin, one (0.8%) failed to declare the presence of sucralose, acesulphame K and aspartame, 3 (2.5%) had excess benzoic acid and one (0.8%) failed to declare the presence of benzoic acid.

The means and ranges of concentrations found are reported for the additives studied. The risk of non-compliance appears to be correlated with the mean concentration expressed as a percentage of the maximum permitted concentration. For example for saccharin this was around 75% while for acesulfame K and aspartame the figure was less than 50%.

Benzoic acid was found in 7 out of 8 samples containing cranberry juice, in which benzoic acid is known to occur naturally. Where present the concentrations found ranged from 4 – 29 mg L^{-1} with a mean of 13 mg L^{-1}.

Failure to disclose the presence of aspartame, a source of phenylalanine, is a risk for sufferers of phenylketonuria (PKU).

The authors suggest that the collection and presentation of data in the manner reported herein, now facilitated electronically by the UK Food Surveillance System, UKFSS, might become a future feature of UKFSS annual reports in Northern Ireland

Introduction

Food additives, including sweeteners and preservatives are strictly regulated in European law[1]. No compounds are permitted for use in food as additives unless they are assessed independently as safe, there is a technological reason for their use and their use does not mislead consumers. In many cases the maximum permitted concentrations are prescribed in law. Guidance[2] has been made available by successive regulatory authorities on the use of additives and it is the responsibility of manufacturers to ensure their use conforms to legal requirements. Further, analysis by Official Food Control (OCL, Public Analyst) laboratories provides reassurance, given an adequate level of sampling that additives are not used in foods where they are not permitted, legal limits are adhered to and information required for safety or consumer choice is in fact given.

Despite this protection, consumer concern about food additives persists. The Food Standards Agency (FSA) has carried out annual consumer attitudes surveys since its inception in 2000. In the years 2000 to 2005 prompted questions yielded concerns about additives from 41% to 45% of respondents. This fell only slightly to 38% for 2006 and 2007[3]. Spontaneously expressed concerns about "additives/preservatives" were recorded from 5% to 10% of respondents in the latter part of this period and were often at or near the top of such unprompted responses. Consumer attitudes have not changed greatly in one of the latest available such report, for 2009[4], with main issues of spontaneous concern for respondents still featuring the use of additives (11%) with 34% of respondents evincing concerns on prompting.

Consumption of the intense sweetener aspartame in particular has generated anecdotal reports of conditions including headaches and upset stomachs. The FSA, while reaffirming that aspartame can be consumed safely, initiated a new study in 2009 focusing on people who have reported reactions to aspartame.[5]

A study[6] commissioned by the FSA and published in 2007 suggested that a mixture of some food colours and benzoate-based preservative could be linked to an adverse effect on the behaviour of hyperactive children.

In view of this continuing interest and in order to place baseline information on the nature and the amounts of intense sweeteners and preservatives in soft drinks on open sale in Northern Ireland in the public domain the authors have collated previously unpublished survey data.

Although the analysis of a wide range of foods for surveillance and enforcement purposes takes place regularly the Northern Ireland Public Analysts Laboratory first conducted a survey, with a view to reporting the collated results, into the prevalence of colours and intense sweeteners in various foods (soft drinks, ice cream and takeaway meals) in 1999[7]. Some soft drinks were found to contain an excessive amount of sweetener and some takeaway meals contained excess colouring matter. It was decided to follow up the soft drinks aspect with a further survey in 2004 funded by *Safe*food[8]. The aims were the analysis of up to 150 samples of soft drinks for intense sweeteners (Acesulfame K, aspartame and saccharin) and preservatives (benzoic acid and sorbic acid).

Regulatory Background

Intense Sweeteners

The term intense sweetener is used to describe an additive with a sweetness many times that of sucrose, which is virtually non-calorific and used solely for its sweetening properties[9]. The general philosophy of Directive 94/35/EC on sweeteners for use in foodstuffs[10] is that the use of intense sweeteners to replace sugar is justified for the production of (i) energy reduced foods, (ii) non-cariogenic foods (iii) foods without added sugars (iv) the extension of shelf life through the replacement of sugar and (v) for dietetic products. The Sweeteners in Food Regulations (Northern Ireland) 1996 that put the Directive into domestic effect allowed a limited range of foods (listed in a Schedule to the Regulations) to contain permitted intense sweeteners and for those set out in Table 1 below and relevant to this work, gave maximum limits.

Table 1 – Permitted intense sweeteners and their maximum concentration limits in Soft Drinks

Serial Number	Permitted Sweetener	Maximum permitted concentration in energy reduced or no added sugar Soft Drinks*, mg L^{-1}
E950	Acesulfame K	350
E951	Aspartame	600
E952	Cyclamic acid	400 reduced to 250 in 2003**
E954	Saccharin	80
E959	Neohesperidine DC	30

** Water-based flavoured drinks, milk- and milk-derivative-based or fruit-juice-based drinks energy-reduced or with no added sugar**;** the maxima (referred to as 'maximum useable dose'*

in the directive) pertain to the drink as consumed after any dilution. For cyclamic acid the sodium and calcium salts may be used and for saccharin the sodium, potassium and calcium salts may be used, the additive levels are calculated as the parent compounds. Saccharin is also permitted up to 100 mgL^{-1} in "Gaseosa": non-alcoholic water based drink with added carbon dioxide, sweeteners and flavourings.

*** By Directive 2003/115/EC of the European Parliament and of the Council of 22 December 2003 see latest consolidated text at reference 10.*

FSA guidance[2] on the meaning of "energy-reduced" states that such foods are:

> *"foods with an energy value reduced by at least 30% compared with the original or a similar food. The legislation does not define the precise basis for this comparison, but wherever possible it should be by reference to one or more products that are currently on the market. If it is not possible to identify a comparable product that is currently on the market, the comparison could be made on the basis of previously marketed products. In an extreme case where it is not possible to identify an actual product, the comparison might be made with a hypothetically equivalent product, the composition of which is based on the use of sucrose rather than permitted intense sweeteners."*

The 1996 regulations and subsequent amendments were revoked except for certain provisions on a transitional basis by the Food Additives Regulations (Northern Ireland) 2009[11] that reference evolving amendments of Directive 94/35/EC. With the exception of cyclamic acid the quantitative limits relevant to this work have not changed. The use of intense sweeteners is prohibited in any food for infants (under 12 months) and young children (between 0 and 3 years).

In practice neohesperidine did not appear to be used to any great extent in soft drinks in Northern Ireland in the periods relevant to this work and only three samples in the 2004 survey contained cyclamic acid. Currently sucralose, thaumatin and the salt of aspartame-acesulfame K are also permitted in soft drinks.

A further aspect of the control of intense sweeteners is the information supplied to consumers. The Food Labelling Regulations (Northern Ireland) 1996 require a list of ingredients, which must include reference to intense sweeteners (and all other functional additives) by way of a category name and the serial number or the name of the additive. In addition to this when a soft drink contains a sweetener or a sugar plus a sweetener the name must disclose this, e.g. "Orange flavour drink with sweetener" or "Raspberry flavour drink with sugar and sweetener". These are examples of legal names and in practice are not usually the most prominent names on the label.

Within the population at large is a small group of people who suffer from an inherited error of metabolism, characterised by the complete or almost complete absence of the enzyme phenylalanine hydroxylase. Excess phenylalanine, an essential amino acid, is excreted from the body in a reaction sequence for which phenylalanine hydroxylase is necessary.

Accumulation of phenylalanine in the blood leads to a variety of neurological symptoms including mental retardation. The disease is known as phenylketonuria (PKU) and is prevented by mandatory blood screening at birth and dietary measures thereafter to limit the intake of phenylalanine[12]. Because aspartame is also a source of phenylalanine all products containing aspartame must be clearly labelled with an indication "contains a source of phenylalanine".

Preservatives

The Miscellaneous Food Additives Regulations (Northern Ireland) 1996 allowed a limited range of foods (listed in a Schedule to the Regulations) to contain permitted preservatives and for those set out in Table 2 below and relevant to this work, give maximum limits. The 1996 regulations and subsequent amendments were revoked except for certain provisions on a transitional basis by the Food Additives Regulations (Northern Ireland) 2009[11] that reference evolving amendments to European Parliament and Council Directive No 95/2/EC of 20 February 1995[13] on food additives other than colours and intense sweeteners. The quantitative limits for benzoic and sorbic acids were unchanged.

Table 2 – Permitted Preservatives and their maximum concentration limits in Soft Drinks

Serial number	Permitted Preservative	Maximum permitted concentration in Soft Drinks (non-alcoholic flavoured drinks) including Freeze Drinks mg L^{-1}
E200	Sorbic Acid	300
E300	Benzoic Acid	150
E300+E200	Benzoic and Sorbic Acids together	250 of Sorbic Acid and 150 of Benzoic Acid

The maxima pertain to the drink as consumed after any dilution. The sodium, calcium or potassium salts may be used; the additive level is calculated as the parent acid. Also currently permitted in soft drinks are sulphur dioxide (with conditions), hydroxybenzoates and dimethyl dicarbonate although for the latter no residue of the compound itself is expected in the product.

Survey Methods

Sampling

Both surveys were agreed with the Northern Ireland Food Liaison Group which represents Environmental Health Departments in Belfast and each of the four groups of Local Authorities in Northern Ireland. Informal sampling was agreed as the basis of the exercise was surveillance rather than enforcement. (Informal sampling: taking a single sample as

opposed to formal sampling where a prescribed procedure is followed including division into three parts to allowing the options of additional analysis by the food business and Government Chemist[14]). For the 2004 survey each group (North, South, East and West) and Belfast was allocated a quota of 30 samples to ensure that sampling would take place throughout Northern Ireland. Sampling advice and a dedicated submission form were prepared (available from the authors on request). The sampling targets were:

- Carbonated soft drinks
- Water based flavoured drinks, energy reduced or with no added sugar
- Cranberry Juices and blends thereof (can contain benzoic acid naturally)
- Alcopops
- Edible ices (especially ice pops)
- Flavoured bottled waters
- Dilute to taste soft drinks
- Fruit based drinks, energy reduced.

Sampling for both surveys was carried out by experienced environmental health officers and pre-packed products were submitted unopened to the laboratory. Sampling for the 2004 survey was carried out in July 2004 from outlets ranging from retail multiples to small local outlets.

Analysis

For the 2004 survey analysis for intense sweeteners was by a UKAS-accredited method as described previously[15]. For the benzoate and sorbate preservatives the same method was adopted but with an aqueous:acetonitrile (80:20) mobile phase. The aqueous portion was 5mM in ammonium acetate and adjusted to pH 4.4 with acetic acid. Detection was at 240 nm. Analytical quality assurance was carried out to the criteria described previously[15], by 10% replication and participation in appropriate proficiency test rounds. Samples in which excess additives were found were each re-analysed on a separate occasion for confirmation purposes. Analysis for the 1999 survey was carried out by similar methods yielding equivalent results.

Results and Discussion

At the time this work was carried out in Northern Ireland results of analysis were classified as follows:

- "Genuine" i.e. compliant with the legal requirements for presence/absence and quantitative limits of additives tested for and satisfying all labelling requirements
- "Adulterated" i.e. not compliant with the legal requirements for presence/absence and quantitative limits of additives tested for or exhibiting serious infringements of labelling requirements or
- "Labelling Irregularity" i.e. minor infringements of labelling requirements.

1999 Survey

The 1999 survey covered colours and intense sweeteners in foods. As part of the work 35 samples of soft drinks were analysed and 20 (57.1%) found to be genuine, 4 (11.4%) were reported as adulterated and 11 (31.4%) were criticised for labelling infringements, mainly the failure to disclose in the name that both sugar and intense sweeteners were present although 2 were criticised because of poor legibility of the legally required information. The adulterated samples failed legal requirements as shown in Table 3.

Information on the occurrence and concentrations of intense sweeteners is given in Table 8 below.

Table 3 - Adulterated Samples, Sweeteners, 1999

No of Samples	Non-compliance with legal requirements
2	Excess saccharin; 87 and 94 mg L^{-1}
1	Failure to declare the presence of saccharin (52 mg L^{-1}) and aspartame (26 mg L^{-1}) – the latter a risk for PKU sufferers
1	No compliant legal name for the product

2004 Survey

Overall 135 samples were received by the laboratory. Of these 14 were duplicate products only one of which was analysed. Of the 121 samples analysed, 103 (85.1%) were found to be genuine, 8 (6.6%) were found to be adulterated and 10 (8.3%) attracted labelling irregularity criticism.

Intense sweeteners

Of the 121 samples analysed for intense sweeteners 107 (88.4 %) were genuine, 4 (3.3 %) were adulterated and 10 (8.3 %) were criticised for labelling infringements. The labelling infringements again included failure to disclose in the name that both sugar and intense sweeteners were present, poor legibility and various spelling errors. In three instances the list of ingredients included acesulphame K but none was present. Bordering on a more serious infringement for one product the phenylalanaine warning was difficult to see being in white type on a light yellow background. The adulterated samples failed legal requirements as shown in Table 4.

Table 4 – Adulterated Samples, Sweeteners, 2004

No. of Samples	Non-compliance with legal requirements
3	Excess saccharin; 81, 86 and 104 mg L^{-1}
1	Failure to declare the presence of sucralose, acesulphame K and aspartame – the latter a risk for PKU sufferers

Table 5 below summarises the quantitative findings. Only 3 samples contained all three intense sweeteners, most samples contained two, either (acesulfame K + aspartame) or (aspartame + saccharin) in about equal numbers. Thus aspartame was the most frequently encountered sweetener. No instances of excessive concentrations of acesulfame K or of aspartame were found. However excessive concentrations of saccharin were found in 3 samples. The average concentration, at the point of consumption, of saccharin at 60 mg L^{-1} was 85 % of its permitted maximum; that for aspartame at 176 mg L^{-1} was 29.3 % of its permitted maximum and that for acesulfame K at 111 mg L^{-1} was 31.7 % of its permitted maximum. The concentration ranges in the samples as intended to be consumed were acesulfame 7 – 321 mg L^{-1}; aspartame 13 – 559 mg L^{-1}; saccharin 11 – 104 mg L^{-1}.

Cyclamic acid was also found in three samples and sucralose in one.

Table 5 – Distribution of intense sweeteners by number and type, 2004

No. of sweeteners present	Total no of samples	Intense sweetener(s) present and no of samples containing it (them)		
1	18 (14.9 %)	Saccharin, 13 (10.7 %)	Aspartame, 4 (3.3 %)	Acesulfame K 1(0.8 %)
2	43 (35.5 %)	Aspartame and Acesulfame 21 (17.4 %)		Saccharin and Aspartame 22 (18.2 %)
3	3 (2.5 %)	Saccharin, Aspartame and Acesulfame		

Preservatives

Of the 121 samples analysed 117 (96.7 %) were genuine and 4 (3.3 %) were adulterated. The adulterated samples failed legal requirements as shown in Table 6.

Of eight samples that claimed to contain cranberry juice and did not list benzoic acid as being present seven were found to contain the compound, assumed to be naturally occurring. The distribution of concentrations was as follows: 0, 4, 7, 7, 11, 22, 26, and 29 mg L^{-1}, with a mean of 13 mg L^{-1}.

Table 6 – Adulterated Samples, Preservatives, 2004

No. of Samples	Non-compliance with legal requirements
3	Excess benzoic acid, 167, 183 and 197 mg L^{-1}
1	Failure to declare the presence of benzoic acid (27 mg L^{-1}), sorbic acid was listed but not present.

Table 7, below, summarises the quantitative findings. Only 20 samples contained both preservatives, most samples (63.6 %) contained benzoic acid. No instances of excessive concentrations of sorbic acid were found, however excessive concentrations of benzoic acid were found in 3 samples. The concentration ranges in the samples as received were benzoic acid 4 – 197 mg L^{-1}; sorbic acid 26 – 223 mg L^{-1}.

Table 7 – Distribution of preservatives by number and type, 2004

Number of preservatives present	Total no of samples	Preservative(s) present and no of samples containing it	
1	67 (55.4 %)	Benzoic acid 57 (47.1 %)	Sorbic acid 10 (8.3 %)
2	20 (16.5 %)	Benzoic acid and sorbic acid	

Comparison of survey findings 1999 and 2004

A comparison is made in Table 8 in respect of the intense sweeteners with the caveat that the number of samples reported on in 2004 (121) was larger than that in 1999 (35).

Saccharin was the most widely used intense sweetener, a position unchanged from the 1999 survey. The mean concentration at which it is incorporated is closer to its maximum permitted concentration than for the other two compounds.

Table 8 – Comparison of Sweeteners Results, 1999 and 2004

Saccharin	Mean concentration and standard deviation of the results mg L^{-1}	Mean as a % of the limit of 80 mg L^{-1}	Range of concentrations found mg L^{-1}
1999	62 ± 20.2	77.5	16 - 94
2004	60 ± 22	75.0	11 - 104

Aspartame	Mean concentration and standard deviation of the results mg L^{-1}	Mean as a % of the limit of 600 mg L^{-1}	Range of concentrations found mg L^{-1}
1999	168 ± 112	28.0	26 - 441
2004	176 ± 126	29.3	13 - 559

Acesulfame K	Mean concentration and standard deviation of the results mg L^{-1}	Mean as a % of the limit of 350 mg L^{-1}	Range of concentrations found mg L^{-1}
1999	155 ± 62	44.3	70 - 303
2004	111 ± 70	31.7	7 - 321

Food Surveillance System (UKFSS)

The FSA has commissioned the development and introduction of a UK Food Surveillance System (UKFSS), a national database that centrally holds a record of all food samples submitted for food analysis by official control laboratories on behalf of local authorities and port health authorities. The system is fully operational in Northern Ireland and Scotland and is currently being implemented across England and Wales[16,17]. The collection and presentation of data in the manner reported herein may now, with the advent of the UKFSS, be facilitated electronically. This may give an opportunity to observe year on year changes in food additive concentrations and track any improvements, or otherwise, with respect to non-compliances.

Conclusions

Food additives consistently attract consumer interest and some concern despite the existence of strict regulation. This paper has described the current regulation of intense sweeteners and preservatives in Northern Ireland and collated previously unpublished survey data.

The mean amounts and ranges of concentrations found are reported for the additives studied. The risk of non-compliance appears to be correlated with the mean concentration as a percentage of the maximum permitted as for saccharin this was around 75% while for acesulfame K and aspartame the figure was less than 50%.

Benzoic acid was found in 7 out of 8 samples containing cranberry juice, in which benzoic acid is known to occur naturally. Where present the concentrations found ranged from 4 – 29 mg L^{-1} with a mean of 13 mg L^{-1}.

Failure to disclose the presence of aspartame, a source of phenylalanine, is a risk for sufferers of phenylketonuria (PKU).

The surveys reported here form a baseline record of the levels of compliance, and information on typical concentrations, which are generally reassuring, but suggest that such surveillance, with enforcement action as required, should continue as isolated problems persist especially with regard to concentrations of saccharin and disclosure of the presence of aspartame. Labelling legibility was a problem in some instances.

The authors suggest that the collection and presentation of data in the manner reported herein, now facilitated electronically by the Food Surveillance System, might be a future feature of the system's annual reports in Northern Ireland.

Tables of the individual results from the 1999 and 2004 surveys are available from the authors on request.

Acknowledgement

The corresponding author gratefully acknowledges the financial sponsorship of *Safe*food, the Food Safety Promotion Board, in carrying out the 2004 survey work.

References

1 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, Official Journal, L **354** 16-33

2 Food Standards Agency (2002). Food Additives Legislation Guidance Notes, available at: http://www.food.gov.uk/multimedia/pdfs/guidance.pdf

3 See list of annual consumer attitude reports, available at: http://www.food.gov.uk/science/socsci/surveys/foodsafety-nutrition-diet/

4 Quarterly Public Attitudes Tracker: December 2009, Food Standards Agency 22 December 2009, available at: http://www.food.gov.uk/multimedia/pdfs/trackerdecem09.pdf

5 Food Standards Agency (2009). Press Release – Aspartame study to begin, available at: http://www.food.gov.uk/news/newsarchive/2009/jun/aspartame

6 McCann D, Barrett A, Cooper A, Crumpler D, Dalen L, Grimshaw K, Kitchen E, Lok K, Porteous L, Prince E, Sonuga-Barke E, Warner JO & Stevenson J (2007). Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children

in the community: a randomised, double-blinded, placebo controlled trial. *Lancet*, **370**, 1560-1567

7 Walker, M.J. Colours and Intense sweeteners in Foods – Food Additives Survey 1999, Department of Health Social Services and Public Safety, N.I. Environmental Health Departments/The Public Analysts Laboratory. Unpublished report.

8 *Safe*food, a body responsible for the promotion of food safety in both jurisdictions of the island of Ireland, http://www.safefood.eu/

9 The Food Labelling Regulations 1996, SI 1499/1996, Regulation 2. Available at: http://www.legislation.gov.uk/uksi/1996/1499/contents/made

10 European Parliament and Council Directive No 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs, OJ No L237 3-12. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:%2031994L0035:EN:NOT

11 The Food Additives Regulations (Northern Ireland) 2009, SRNI 416/2009. Available at: http://www.legislation.gov.uk/nisr/2009/416/introduction/made

12 Medline Plus, U.S. National Library of Medicine, National Institutes of Health (2010) Phenylketonuria. Available at: http://www.nlm.nih.gov/medlineplus/ency/article/001166.htm

13 European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and intense sweeteners, OJ L61 1-40. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0002:en:NOT

14 The Food Safety (Sampling and Qualifications) Regulations 1990, SI 2463/1990. Available at: http://www.legislation.gov.uk/uksi/1990/2463/contents/made

15 Walker MJ, McShane J, Thorburn Burns D, Canavan P and Flanagan A (2009). A Cross-border Method Validation for the Determination of Intense sweeteners in Soft Drinks, J. Assoc. Publ. Analysts (JAPA Online) **37**, 1-13. Available at: http://www.apajournal.org.uk/Volume_36-37/JAPA_Vol_37_pg_1-13/japa_vol_37_pg_1-13.html

16 Food Standards Agency, UK Food Surveillance System (UKFSS) http://www.food.gov.uk/enforcement/monitoring/fss/

17 L. Cree, M. Reid (2009). Development of the UK food samples surveillance system, *Public Health*, **123**, 89-94