A Surveillance Study of the Sweetener Sucralose (E 955) in Irish Retail Products

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Summary

The Food Safety Authority of Ireland (FSAI), in conjunction with the Public Analysts Laboratory Service, has carried out a surveillance study on products containing the artificial sweetener sucralose available on the Irish market in order to establish levels of compliance with existing legislation.

Twenty-nine samples comprising of flavoured waters, soft drinks, alcoholic drinks, shakes, breakfast bars and other confectionery were analysed in this survey. Samples purchased were "ready to eat/drink", and were analysed as such. All samples analysed were in compliance with legislative limits established for sucralose in food. Intakes of sucralose by the Irish population, estimated from food consumption data for adults and levels of the sweetener found in the products surveyed, are well below the Acceptable Daily Intake of 0 – 15 mg/kg body weight established by the EU Scientific Committee for Food in 2000.

Introduction

The Food Safety Authority of Ireland (FSAI) has a statutory responsibility to ensure the safety of food consumed, distributed, produced and sold on the Irish market. In this respect, the FSAI coordinates the collation of food safety surveillance information from laboratories run by its official agents, the Health Service Executive, the Department of Agriculture and Food, the Department of Communications, Marine and Natural Resources, the Marine Institute and the local authorities. This report provides the results of a targeted surveillance study on levels of the artificial sweetener sucralose in foods available on the Irish market. The study also provides an assessment of the intake of sucralose by Irish consumers of products containing the sweetener.

Background

Intense sweeteners are used to replace sugar in a wide range of sugar-free and reduced calorie foods and have benefits for those consumers wishing to reduce their sugar or calorie intake and for people suffering from diabetes. Sucralose (*trichlorogalactosucrose)* is a sweetener manufactured by controlled chlorination of sucrose and is approximately 500-600 times sweeter than sugar.

In 2000, the European Union Scientific Committee on Food (SCF) assessed the data on the safety of sucralose and concluded that sucralose is acceptable as a sweetener for general food use and set an Acceptable Daily Intake (ADI) of 0-15 mg/kg body weight.

The use of sweeteners in foodstuffs is regulated by European legislation[1] and only approved sweeteners may be used in food specified in the legislation. However, a Member State may in accordance with the legislation grant national authorisation for the use of a new sweetener for a temporary period of two years. The FSAI granted a temporary national authorisation for sucralose in January 2003. Authorising an additional intense sweetener has the benefits of offering consumers and the food industry the possibility to choose between a wider variety of sweeteners, thus reducing the intake of the single sweeteners.

At the time the FSAI granted the temporary national authorisation, sucralose was approved in several other countries world wide, including the UK, Canada, Australia, Japan and the United States of America.

Sucralose can be used in a wide variety of products as listed in Table 1.

Table 1: Products permitted to contain sucralose

table-top sweeteners	fruit spreads
processed fruit	milk products
carbonated beverages	frozen desserts
non-carbonated beverages	salad dressings
chewing gum	dry-mix products
baked goods	

The authorisation granted in Ireland was for the use of sucralose as or in a tabletop sweetener and as a sweetener in a range of food categories as listed in Annex 1. The levels of sucralose permitted in these foodstuffs are also shown in Annex 1. When sucralose is used as a tabletop sweetener, the sales description of the sweetener shall include the term "sucralose-based table-top sweetener", and when included in other food products it should be listed as "sweetener: sucralose", in accordance with the general labelling provisions for ingredients laid down in the Labelling Directive 2000/13/EC.

Since the FSAI granted the temporary national authorisation, sucralose has been included in the list of approved food additives, under the EU legislation on sweeteners (Directive 2003/115/EC) for application in a wide range of foods and drinks. Under this legislation, Member States are required to establish a system of regular surveys to monitor sweetener consumption, and this study was undertaken to enable Ireland to meet its obligations in this respect.

[1] Directive 94/35/EC on sweeteners for use in foodstuffs together with the Framework Directive on Food Additives, 89/107/EC. These Directives are implemented in Ireland by S.I. No. 437 of 2000. Directive 94/35/EC has been amended by Directive 2003/115/EC, which is implemented in Ireland by S.I. No. 61 of 2005.

Study Details

A total number of 29 samples were taken by officers of the FSAI and forwarded to the Dublin Public Analyst Laboratory (PAL) for analysis. Samples were selected following information received from industry on the use of the sweetener in food products. The sampling occurred in November 2004 and March 2005. Samples were taken at retail level and comprised the following:

- Flavoured waters 8 samples
- Soft drinks/Juice drinks 11 samples
- Alcoholic drinks 2 samples
- Shakes 3 samples
- Breakfast bars/Confectionery products 5 samples

Methodology and Reporting Limits

The determination of sucralose in food products is usually achieved by extraction of the sucralose into a polar solvent such as water or methanol, followed by High Performance Liquid Chromatography (HPLC) analysis with refractive index detection. Solid food products are usually ground or homogenised to facilitate extraction. Water based products such as beverages can be analysed without an extraction step, but carbonated products must be de-carbonated prior to analysis. Generally some form of sample clean up is required prior to analysis to separate and remove potentially interfering components and this is usually achieved using solid phase extraction. The limit of quantitation (LOQ) in the Dublin PAL laboratory is 50 mg/L for beverages.

Results

(a) Levels of sucralose in products available on the Irish market

The study showed that levels of sucralose in the 21 products submitted for analysis in November 2004 were well below the legal limits laid down in the temporary national authorisation, whilst the remaining eight samples submitted in March 2005 were in conformance with the limits laid down in Directive 2003/115/EC. The results for the individual samples are given in Table 2.

Table 2: Levels of sucralose detected in selected Irish retail products

Type	Sucralose Concentration	Maximum Usable Dose
Flavoured Waters		
Lemon and Lime Flavoured Water	110 mg/l	300 mg/l
Apple and Cranberry Flavoured Water	90 mg/l	300 mg/l
Raspberry and Blackberry	90 mg/l	300 mg/l
Grapefruit and Lime	160 mg/l	300 mg/l
Orange Spring Water Drink	77 mg/l	300 mg/l
Strawberry and Vanilla Spring Water	120.5 mg/l	300 mg/l
Blackcurrant and Blackberry Spring Water	111.7 mg/l	300 mg/l
Orange and Tangerine Spring Water	118.1 mg/l	300 mg/l
Jamaican Ginger Beer Flavoured Spring Water	163.8 mg/l	300 mg/l
Juices		
Cranberry Juice	80 mg/l	300 mg/l
Cranberry and Blackcurrant Juice	80 mg/l	300 mg/l
Cranberry and Mango Juice	110 mg/l	300 mg/l
Cranberry and Raspberry Juice	70 mg/l	300 mg/l
Soft Drinks		
Diet Lemon	170 mg/l	300 mg/l
Diet Orange	240 mg/l	300 mg/l
Tropical Orange	285 mg/l	300 mg/l
Citrus Revive	9.5 mg/l	300 mg/l
Berry Boost	8.4 mg/l	300 mg/l
Grapefruit Rehydration Drink	99.8 mg/l	300 mg/l
Breakfast Bars/Confectionery		
Apple Crisp	100 mg/kg	1000 mg/kg
Chocolate Chip Crisp	100 mg/kg	1000 mg/kg
Strawberry Crisp	170 mg/kg	1000 mg/kg
Chocolate and Hazelnut Crunch	200 mg/kg	1000 mg/kg
Chocolate Bar	340 mg/kg	1000 mg/kg
Alcoholic Drinks		
Diet Lemon Alcopop	120 mg/l	250 mg/l
Cider	30 mg/l	50 mg/l
Shakes		
Vanilla Flavour	150 mg/l	300 mg/l
Chocolate Flavour	160 mg/l	300 mg/l
Strawberry Flavour	150 mg/l	300 mg/l

(b) Estimation of the intake of sucralose by Irish consumers and comparison with the Acceptable Daily Intake

The North:South Ireland Food Consumption Survey (NSIFCS), which investigated habitual food and beverage consumption, lifestyle, health indicators and attitudes to food and health in a representative sample (n=1379) of the 18-64 year old adult population in the Republic of Ireland and Northern Ireland during 1997-1999 was used to estimate the exposure of the Irish population to sucralose. The extensive electronic database which has been compiled from the NSIFCS survey is the most complete and up-to-date collection of food consumption data available for adults in the island of Ireland. The software tool CREMe (Central Risk and Exposure Modelling e-Solution) was then used to estimate the exposure to sucralose from the samples surveyed. The CREMe software solution incorporates scientifically validated and peer reviewed models and is delivered as a secure web service with access to high performance computing. This allows CREMe to provide realistic and accurate exposure assessments to food products and or chemical ingredients. This software incorporates the results of the NSIFCS survey described above.

The results from the CREMe exposure simulation showed (see Table 3) that the average intake of sucralose among the Irish adult population was 0.0307 mg/kg bw/day. This figure increased to 0.190 mg/kg bw/day and 0.352 mg/kg bw/day for the 95th percentile and 97.5 percentile consumers respectively. The ADI[2] of sucralose is 0-15 mg/kg bw/day and the average weight of Irish consumers is 70 kg for adults. Therefore, when the ADI is taken into account and compared with the results found in the intake survey of 0.0307 mg/kg bw/day, 0.190 mg/kg bw/day and 0.352 mg/kg bw/day the results indicate that all adult consumers of sucralose, even high consumers in the population, have a dietary intake well below the ADI for sucralose.

Table 3: Estimated intakes (mean, 95%ile and 97.5%ile) of sucralose by the Irish population

	Mean intake (mg/kg/day)	95th%ile intake (mg/kg/day)	97.5%ile intake (mg/kg/day)	ADI mg/kg bw/day	% ADI for 97.5%ile consumers
Adults (70 kg bw)	0.0307	0.190	0.352	0-15	2.35%

Although intakes could not be estimated for young children in this study, as there are currently no food consumption data for young children in the North:South Ireland Food Consumption Database (note: a children's survey has just been completed and will shortly be published), it is important to note that young children are more likely to exceed the ADI for sucralose and other food additives than adults, due to their higher consumption of food per kilogram of body weight.

[2] ADI: Acceptable Daily Intake. The amount of sucralose that can be consumed over a lifetime without incurring any appreciable health risk

However, in this survey some of the products were reduced calorie or alcoholic products and therefore would be targeted at the diet and adult market rather than young children.

Conclusion

The levels of sucralose measured in a range of products in this survey indicate that manufacturers using this sweetener in their product formulations are aware of the statutory maximum levels in food and beverages. The survey did not reveal any breaches of the sweeteners legislation with respect to usage of sucralose in the products available on the Irish market at the time of the survey. Exposure estimates based on the levels measured in these products indicate that the mean intake of the Irish population to sucralose was 0.0307 mg/kg bw/day, which increased to 0.190 mg/kg bw/day and 0.352 mg/kg bw/day for the 95th and 97.5 percentile consumers respectively. These findings support the conclusion that exposure of Irish consumers to sucralose is within the acceptable range and does not raise any concerns for consumer health.

However, since this survey was carried out there are now a larger number of products on the Irish market containing sucralose. FSAI therefore considers that further monitoring of usage of this sweetener and exposure of the Irish population including young children to sucralose and to artificial sweeteners in general is necessary, and will be carrying out further studies of this nature.

Acknowledgement

The FSAI would like to thank CREMe Software Ltd for allowing us use of their website in order to estimate the exposure of the Irish population to sucralose. This software is available on a trial basis to the FSAI. Further information on this software can be found at the following web address: http://www.cremesoftware.com/

CREMe

ANNEX 1

EC No	Name	Foodstuffs	Maximum usable level
E 955	**Sucralose**		
NON-ALCOHOLIC DRINKS			
Water-based flavoured drinks, energy-reduced or with no added sugar			300 mg/l
Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar			300 mg/l
DESSERTS AND SIMILAR PRODUCTS			
Water-based flavoured desserts, energy-reduced or with no added sugar			400 mg/l
Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar			400 mg/kg
Fruit- and vegetable-based desserts, energy-reduced or with no added sugar			400 mg/kg
Egg-based desserts, energy-reduced or with no added sugar			400 mg/kg
Cereal-based desserts, energy-reduced or with no added sugar			400 mg/kg
Fat-based desserts, energy-reduced or with no added sugar			400 mg/kg
"Snacks": certain flavours of ready to eat, pre-packed, dry, savoury starch products and coated nuts			200 mg/kg
CONFECTIONERY			
Confectionery with no added sugar			1000 mg/kg
Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar			800 mg/kg
Starch-based confectionery, energy-reduced or with no added sugar			1000 mg/kg
Cornets and wafers, for ice cream, with no added sugar			800 mg/kg
Essoblaten			800 mg/kg
Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar			400 mg/kg
Breakfast cereals with a fibre content of more than 15% and containing at least 20% bran, energy reduced or with no added sugar			400 mg/kg
Breath-freshening micro-sweets with no added sugar			2400 mg/kg
Strongly flavoured freshening throat pastilles with no added sugar			1000 mg/kg
Chewing gum with no added sugar			3000 mg/kg
Energy-reduced tablet form of confectionery			200 mg/kg
Cider and Perry			50 mg/l
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine			250 mg/l
Spirit drinks containing less than 15% alcohol by volume			250 mg/l
Alcohol-free beer or with an alcohol content not exceeding 1.2% vol			250 mg/l
'Bière de table/Tafelbier/Table beer' (original wort content less than 6%) except for 'Obergäriges Einfachbier'			250 mg/l
Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH			250 mg/l
Brown beers of the '*oud bruin'* type			250 mg/l
Energy-reduced beer			10 mg/l
Edible ices, energy-reduced or with no added sugar			320 mg/kg
Canned or bottled fruit, energy-reduced or with no added sugar			400 mg/kg
Energy-reduced jams, jellies and marmalades			400 mg/kg
Energy-reduced fruit and vegetable preparations			400 mg/kg
Sweet-sour preserves of fruit and vegetables			180 mg/kg
Feinkostsalat			140 mg/kg
Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs			120 mg/kg
Energy-reduced soups			45 mg/l
Sauces			450 mg/kg
Mustard			140 mg/kg
Fine bakery products for special nutritional uses			700 mg/kg
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 1996/8/EC			320 mg/kg
Dietary foods for special medical purposes as defined in Directive 1999/21/EC			400 mg/kg
Food supplements as defined in Directive 2002/46/EC, supplied in liquid form			240 mg/kg
Food supplements as defined in Directive 2002/46/EC supplied in solid form			800 mg/kg

Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	2400 mg/kg