Reprinted from

FOOD ADDITIVES AND CONTAMINANTS

Vol. 14, No. 8, pp. 791–802

EVALUATION OF THE BUDGET METHOD FOR SCREENING FOOD ADDITIVE INTAKES

Judith S. DOUGLASS[1], Leila M. BARRAJ[1], David R. TENNANT[2], Wesley R. LONG[1], and Christine F. CHAISSON[1]

[1] Technical Assessment Systems, Inc., Washington DC 20007 USA
[2] TAS International, Malvern WR14 2AZ UK

ILSI

International Life Sciences INSTITUTE

Prepared under the responsibility of the
ILSI Europe Food Chemical Intake Task Force

Food Additives and Contaminants, 1997, Vol. 14, No. 8, 791–802

Evaluation of the Budget Method for screening food additive intakes

Judith S. Douglass†, Leila M. Barraj†, David R. Tennant‡§, Wesley R. Long† and Christine F. Chaisson†

† *Technical Assessment Systems, Inc., Washington DC 20007, USA*
‡ *TAS International, Malvern WR14 2AZ, UK*

(Received 4 April 1997; accepted 8 April 1997)

The Budget Method, originally developed for determining food additive use limits, has been proposed as a tool for screening food additive intakes to establish monitoring priorities. Theoretical Maximum Daily Intake (TMDI) estimates derived using the Budget Method rely on assumptions regarding physiological requirements for energy and liquid and on the energy density of food rather than on food consumption survey data. This report summarizes work performed to determine the validity of Budget Method assumptions and to assess the potential for error in assigning monitoring priority based on Budget Method results. Budget Method assumptions regarding energy and liquid intake were compared with data from UK, German and US nationwide food consumption surveys. It was found that the Budget Method assumptions of energy intake and liquid intake are higher than mean intakes reported in surveys. The Budget Method assumption regarding energy density of foods also was found to be a slight overestimate. Budget Method TMDIs for case study additives were in each case larger than survey-based 95th percentile per capita *additive intake estimates. Based on these results, the Budget Method appears to be a suitably conservative screen for establishing additive monitoring priorities based on potential lifetime average intakes.*

Keywords: Food additives, intake, exposure, energy intake, risk assessment, monitoring

§To whom correspondence should be addressed.

Introduction

European Union (EU) Directives 94/35/EC, 94/36/EC and 95/2/EC require each Member State to monitor the consumption and usage of food additives. The European Commission was not empowered by these directives to specify how the Member States should fulfil this obligation. However, the Commission does have a role in co-ordinating the national programmes and is called upon to submit a report to the European Parliament. The Commission recognizes that a high degree of co-ordination is essential if its report to the European Parliament is to provide a coherent summary of the overall situation in the European Union.

A variety of additive monitoring methods has been discussed. A mega-database of information on additive concentrations in foods has been proposed but such a database is unlikely to be established in time to meet the requirements of the EU Directives (Nutriscan 1994). *Ad hoc* chemical analyses might be appropriate in specific applications, but would be impractical for effective monitoring of all chemicals. Targeted surveys of use and/or intake of specific additives can be (and have been) performed to provide important data for monitoring but the cost of monitoring the use of all additives in all foods by chemical analysis would be prohibitively expensive.

Many of the methods in use for determining intakes of additives rely on food production statistics or on national food consumption survey data. In general, estimates of additive intake from food consumption data must be generated by experts who understand the nuances and limitations of survey techniques and know the details of the particular survey. The most accurate estimates are generated using data on consumption of specific foods by individuals and such data are not widely available. Additive intake estimation using food consumption data, while requiring fewer resources than the analytical approaches discussed above, still requires significant resources and is considered impractical for use with every additive.

Although Member States are not required to use a common monitoring approach, the development of a science-based but practical monitoring system is a formidable task which they all face. Eleven Member States and Norway, acting under the EU Scientific Co-operation Directive (SCOOP), have been working together to develop a tiered system for prioritizing needs for monitoring specific additives. The Codex Alimentarius Commission Committee on Food Additives and Contaminants has considered such a system (CX/FAC/96/6) for determining whether the additive uses listed in the Codex General Standard for Food Additives (GSFA) pose any risk to public safety.

The 'tiers' described in the Codex protocol are essentially additive intake estimation methods which progress in complexity and data requirements. These methods are intended to produce progressively more accurate estimates of additive intake, although they have not been validated for this purpose. Where results of analyses in a low level tier indicate that an ADI is unlikely ever to be exceeded, the screen eliminates the additive from further consideration, thus conserving valuable resources. Resources can then be focused toward additives for which the potential for exceeding the ADI cannot be excluded with the present conditions of use and assumptions used in the assessment. In these cases, additives are further evaluated using more complex but less conservative intake estimation methods.

The lower level tiers are designed to be ultra-conservative in order to minimize the risk that an additive, for which there is a possibility that the take may exceed the ADI, is erroneously eliminated from further consideration. However, it must be emphasized that these tiers are tools for establishing monitoring priorities rather than tools for risk assessment: results from screening tests should never be interpreted as realistic estimates of intake.

An adaptation of the Budget Method, developed by Søren Hansen (1966) of the National Food Agency of Denmark for determining maximum use levels for food additives, has been proposed by Codex as the Tier 1 screening step. Use of the Budget Method in the manner proposed by Codex is intended to yield a worst-case additive intake estimate, the 'theoretical maximum daily intake' (TMDI).

The Budget Method provides the basis for a simple, inexpensive screening method for intakes because it relies on assumptions regarding physiological requirements for energy and liquid and on energy density of food rather than on food consumption survey data. The TMDI is calculated by assuming that all foods contributing to the energy intake, and all beverages contributing to the liquid intake, will contain the additive at maximum permitted use levels. Under the Codex proposal, an additive is said to 'pass' the Budget Method screen if the calculated TMDI is lower than the additive's acceptable daily intake (ADI).

The Budget Method may also be an appropriate screening method for determining priorities for additive monitoring required under EU Directives 94/35/EC, 94/36/EC and 95/2/EC. Before it can be accepted in the EU for such a purpose, however, the underlying assumptions must be examined to evaluate the potential for error in the use of results to establishing monitoring priorities. Clearly, the Budget Method must *over*-estimate intake in order to minimize Type II (false negative) errors: a false indication could result in unchecked use of a substance which should have been a priority for monitoring. Conversely, Type I (false positive) errors should be minimized to prevent unnecessary expenditure of time and resources in pursuit of more detailed intake estimates.

This report summarizes work performed by TAS International, at the request of the International Life Sciences Institute Europe (ILSI Europe), to evaluate the validity of assumptions on which the Budget Method is based and to assess the potential for Type I and Type II errors in using results to establish additive monitoring priority.

The Budget Method

The Budget Method was designed to convert food additive ADIs into 'ceilings of use' calculated on the basis of maximum intakes of food and beverages potentially containing the additives (Hansen 1966, 1979). In budget calculations for additives used in both solid foods and beverages, the ADIs are divided into two fractions. The proportion of the ADI allocated to food and the proportion allocated to beverages are decided upon arbitrarily to accommodate technological requirements.

In developing the Budget Method for determining ceilings for additives used in foods, Hansen started from a basic assumption that from the time a child begins eating food potentially containing additives, energy intake will not exceed 100 kcal/kg body weight/day. He supported this assumption with data showing an inverse relationship between age and energy requirements per unit body weight, noting that 'there is a remarkable steep decline during the first few years of life which enables us to identify a landmark or starting point for estimation of intake, namely 100 kcal per kg of body weight per day'. Hansen used a conversion factor of 2 kcal/g for 'average food including milk but excluding other beverages' to estimate the maximum amount of foods containing an additive as 50 g food/kg body weight/day. Additive ceilings can then be calculated as being equal to *one ADI per 50 g of food or (ADI × 20) mg/kg food.*

Hansen recognized that by assuming an intake of 50 g food/kg body weight/day, with all food potentially containing all additives, additive ceilings calculated using the Budget Method could fall below technologically effective levels. Believing that the ADI safety factors cover differences between adults and children, Hansen stated that he was 'unduly cautious' in basing calculations on very young children, and judged that 'a factor of 2 should be permissible' for adjusting food additive ceilings to *(ADI × 40) mg/kg food.*

Hansen also proposed adjustment of additive ceilings to technologically effective levels, where necessary, by restricting use of relevant additives to half or a quarter of the 'full horizon' of foods, using assumptions related to proportions of processed food in the food supply. These assumptions have been interpreted as meaning that processed food does not represent more than 50% of total maximum food intake and that half of this is represented by processed milk, meat, fish, poultry, vegetables, and cereal products less likely to contain additives (Hallas-Møller 1987, Bär and Würtzen 1990). Food additive ceilings would then be *(ADI × 80) mg/kg food or (ADI × 160) mg/kg food*, depending on whether the predicted additive use pattern included processed milk, meat, fish, poultry, vegetables and cereal products. The conversion from 'additive ceiling' to TMDI and the factors involved are described in table 1.

In determining ceilings of use for additives used in beverages, Hansen reviewed the literature on liquid intakes of infants, children, and adults in hot climates and concluded that 'it is unlikely that any person will ever drink more than 100 ml/kg body weight/day from beverages, excluding milk'. Hansen also referred to data on liquid requirements, stating that 'if we choose the recommended liquid intake at the age of two, 100 ml per kg body weight per day, as the basis for our calculations of intake we cover the child and we also cover the adult'. Hansen proposed adjustment of additive ceilings to technologically effective levels, where necessary, by applying factors to double or redouble the ceilings, considering competition among beverages. In assessing additive ceilings for soft drinks, the assumption has been that soft drinks account for 25% of the 100 ml/kg body weight/day maximum intake (Hallas-Møller 1987, Bär and

Table 1. Assumptions made in screening additive intakes using the Budget Method: additives used in food.

1 Maximum energy intake by young children consuming table foods is 100 kcal/kg body weight/day.
2 Maximum energy intake over the course of a lifetime is 50 kcal/kg body weight/day.
3 50 kcal = 25 g food.

If:	*Then the Theoretical Maximum Daily Intake (TMDI) of an additive can be calculated as:*
4 The additive is used in foods other than baby foods, and the maximum amount of food required to meet energy requirements is: 25 g per kg body weight	$\frac{\text{Maximum use level (mg additive/kg food)}}{40}$ (NB: 25 g food = 1/40 kg food)
5 50% of foods consumed are processed.	$\frac{\text{Maximum use level (mg additive/kg food)}}{80}$
6 The additive is used in processed foods other than those considered to be important in the daily diet (e.g. dairy, meat, fish, poultry, vegetable or cereal products).	$\frac{\text{Maximum use level (mg additive/kg food)}}{160}$

Table 3. Food consumption survey data used in Budget Method validation.

United Kingdom
Data used in the analyses were taken from the following summary sources of survey data published by the Ministry of Agriculture, Fisheries and Food:

- *Food and Nutrient Intakes of British Infants Aged 6–12 Months*; 1986; 488 infants; based on 7-day food intake records.
- *National Diet and Nutrition Survey: Children Aged 1½–4½ years*: July 1992 and June 1993; 1675 children; based on 7-day food intake records.
- *The Diets of British School Children*; 1983; 3581 children ages 10–11 and 14–15; based on 7-day food intake records.
- *The Dietary and Nutritional Survey of British Adults*: October 1986–August 1987; 2197 adults aged 16 to 64; based on 7-day food intake records.

Former West Germany
National Consumption Study (NVS); October 1985–January 1989. Seven-day weighed intake data were collected from over 25 000 individuals 4 years of age and older, using a system consisting of over 6000 food codes. Data used in the present analyses were taken from a dataset containing records of average daily intakes of foods in 90 summary food groups by individual survey respondents.

United States
US Department of Agriculture 1989–90, 1990–91 and 1991–92 Continuing Surveys of Food Consumption by Individuals (CSFII). Together, the CSFII surveys measured dietary intake of over 11 000 individuals over a 3-day period. Although these data clearly are not directly reflective of European food intake patterns, it was felt that the extensive information on intake by individuals could be of potential value in examining basic Budget Method assumptions regarding food additive intakes. For example, neither the UK surveys nor the German survey collected data on individuals in all age groups; the US data provide supplementary data on total population intakes.

liketime. Additive intakes are unlikely to be sustained at high levels throughout life. The validity of the underlying assumptions was therefore assessed on the basis of population averages rather than on high level intakes in order to be consistent with the Budget Method approach.

Budget Method assumptions regarding proportions of the diet accounted for by processed foods potentially containing additives were not tested due to limitations in the availability of European survey data. The UK surveys were conducted on selected age groups, and results available for analysis were summarized for age groups and broad food groups. The West German survey results used were summarized by food group, but represented individual consumption by all respondents in the survey population (4 years of age and older). The US results used represented consumption of specific foods by each of the survey respondents. Analyses were conducted on four representative age bands corresponding to the UK food consumption survey data.

Case studies

To evaluate the potential for Type I and Type II errors in use of the Budget Method as a screening tool, case studies were conducted for two food additives with different characteristics and proposed uses (tables 4 and 5). The additives are hypothetical. However, maximum permitted use levels in specific food groups were selected to reflect realistic use levels. Sample Food Additive 1 was designed to be representative of an additive used at consistent levels in a broad range of foods consumed by a significant portion of the population (e.g. a stabilizer or preservative). Food Additive 2 was designed to be representative of an additive used in varying

Table 4. Case Study Additive 1: use limits.

	Additive use limits	
	Food category	Use limit (mg/kg food)
Additive 1:	Breads	50
Used at consistent levels	Baked products	50
in a broad range of foods	Pastas	30
consumed by a significant	Cereals	50
portion of the population	Rice	30

Table 5. Case Study Additive 2: use limits.

	Additive use limits	
	Food category	Use limit (mg/kg food or mg/l beverage)
Additive 2:	Soft drinks	350
Used in varying con-	Biscuits	1000
centrations in a range	Confectionery	500
of foods consumed by		
specific segments of the		
population		

Table 2. Assumptions made in screening additive intakes using the Budget Method: additives used in beverages.

1 Maximum intake of liquids (other than milk) is 100 ml/kg body weight/day.	
If:	*Then the Theoretical Maximum Daily Intake (TMDI) of an additive can be calculated as:*
2 The additive is used in all non-milk beverages, and the maximum amount of non-milk beverages consumed is $\frac{100\text{ml}}{\text{kg body weight}}$ (100 ml = 1/10 litre).	$\frac{\text{Maximum use level (mg additive/l beverage)}}{10}$
3 The additive is used only in soft drinks, and maximum soft drink intake is 25% of non-milk beverage intake.	$\frac{\text{Maximum use level (mg additive/l beverage)}}{40}$

Würtzen 1990). Assuming a density of 1 g/ml, the ceiling for additive use in soft drinks can be calculated as *(ADI × 40) mg/kg beverage*. The conversion from the beverage 'additive ceiling' to TMDI and the factors involved are described in table 2.

The validity of Budget Method assumptions for calculating additive ceilings of use has been evaluated on a limited basis by Hallas-Møller (1987) using the results of a 1985 Danish food consumption survey of adults (National Food Agency of Denmark 1986). Assumptions regarding maximum food intake (50 g/kg body weight/day) and the proportion of processed food consumed (50%) were judged valid for 90% of adults. However, up to 25% of adults consumed more 'high additive' foods than the 25% of total foods assumed by Hansen.

Hallas-Møller found the Budget Method assumption regarding maximum liquid intake (100 ml/kg body weight/day) to be valid for 99·6% of Danish adults. Bär and Würtzen (1990) reviewed liquid intake data from the US and several European countries, and concluded that 'a daily liquid consumption of 100 ml/kg body weight is not a reasonable starting point for budget calculations. Instead it appears that a daily liquid intake of 50 ml/kg will cover the needs under extreme conditions, and of heavy consumers'.

Bär and Würtzen (1990) examined the value and limitations of the Budget Method for calculating additive use ceilings using intense sweeteners as examples. The authors found that intense sweetener intakes estimated using data from targeted surveys of sweetener intake by several European populations were far below intakes predicted by the Budget Method. The authors proposed several modifications including alternate reference points and correction factors to compensate for competing additives with similar functional uses. They noted a potential need for additional correction factors to be used with additives applied in limited types of foods and with additives which have self-limiting properties.

The proposal to use the Budget Method as Tier 1 of the Codex GSFA safety evaluation calls for calculation of TMDIs based on maximum current additive use levels. Assumptions made in TMDI calculations are listed in tables 1 and 2. Use of the Budget Method in EU screening to establish monitoring priority would, if accepted for this purpose, involve similar assumptions and calculations. However, the Budget Method assumptions to be used in these calculations were developed for purposes other than those proposed, and must be carefully evaluated for relevance to the proposed applications.

Methods

Evaluation of underlying assumptions

To evaluate whether Budget Method assumptions regarding energy intake, energy density of food, beverage consumption and soft drink consumption provide a valid basis for screening additive intakes to determine priority for monitoring, TAS examined intake data from nation-wide food consumption surveys of individuals conducted in the United Kingdom, the former West Germany, and the United States (table 3). The Budget Method assumes that ADIs for additives relate to average intakes over a

Table 6. Budget Method TMDI estimates for Case Study Additives 1 and 2.

Food additive	Use level in calculation	Budget method factor	TMDI (mg/kg body weight)	
1	50 mg/kg	80		0·63
2	350 mg/l	40	8·75	15·00
	1000 mg/kg	160[a]	6·25	

[a] Approach recommended by Hallas-Møller (1995)

concentrations in a range of foods consumed by specific segments of the population (e.g. an intense sweetener).

The Budget Method TMDI for Additive 1 was calculated assuming that up to 50% of consumed foods would contain the additive, using the food intake factor of 80 derived in the previous section (table 6). The TMDI for Additive 2 was calculated allocating half of the budget to soft drinks and half to 'high additive' solid foods (biscuits and confectionery), using a liquid intake factor of 40 and a food consumption factor of 160.

Food consumption survey-based intake estimates for Additives 1 and 2 were calculated as precisely as possible given the particular limitations of the surveys. Additive use levels were applied to food consumption data in the categories shown in tables 7 and 8.

The Budget Method is generally assumed to provide a conservative estimate of the upper limit of lifetime intake for all consumers. In order to test this, high level (95th percentile) intakes of adults (16–64 years) were used for comparison with Budget method TMDIs.

Limitations of the survey data used in these analyses precluded calculation of per-user intakes. However, because it was assumed that all people will be consumers of the additives in question at some point in their lifetimes, *per capita* estimates were judged to be representative of lifetime intakes. It was also assumed that extreme high-level user intakes on the per kg body weight basis would not be maintained throughout the course of a lifetime, and that 95th percentile *per capita* intakes would provide a reasonable picture of upper level intake. Where available survey data did not permit assessment of 95th percentile *per capita* intakes, these intakes were estimated using the Bernier method (Bernier *et al.* 1994), by taking three times the mean.

Results

Validation of Budget Method assumptions regarding energy intake, energy density of foods, beverage consumption and soft drink consumption

Energy intake. Budget Method assumptions regarding maximum energy intake are 100 kcal/kg body weight/day for 1-year old children and 50 kcal/kg body weight/day over a lifetime.

Mean energy intakes reported in the UK, German and US surveys are shown in table 9. The energy intake distribution for the total population and for 1-year olds, based on US survey data, is presented in figure 1.

Energy intakes reported in the UK, German and US surveys are comparable across populations; the results confirm that as with energy requirements, daily energy intake, adjusted by body weight, decreases with age. The mean energy intake for infants falls within the upper tail for energy intake for the total population. The survey results therefore indicate, at least in the populations examined, that the Budget Method assumptions of 100 kcal/kg body weight energy intake for 1-year olds and of 50 kcal/kg body weight for the general population tend to overestimate actual lifetime intakes of 91–96 kcal/kg body weight for 1-year olds and 35–39 kcal/kg body weight for the general population.

The extent of the apparent Budget Method overestimate of intake may not be significant, as under-reported energy intake has been documented in research on various survey techniques (Bingham 1987, Schoeller 1990, Black *et al.* 1993, Haroldsdottir *et al.* 1993). Using a low ratio of energy intake to estimated basal metabolic rate as the criterion for under-reported energy intake, Briefel *et al.* (1995) found under-reporting in two major US surveys, one of which was the CSFII used in analyses for the present report.

Energy density of food. In developing the Budget Method, Hansen (1966, 1979) assumed that 50 grams of food had an energy value equal to 100 kcal,

Table 7. Case Study Additive 1: additive use categories and corresponding food categories in survey data summaries.

Additive use categories	Food categories in survey data summaries					
	UK					
	Food and Nutrient Intakes of British Infants Aged 6–12 Months, 1986	*National Diet and Nutrition Survey: Children Aged $1\frac{1}{2}$–$4\frac{1}{2}$ years*, July 1992 and June 1993	*The Diets of British School Children*, 1983	*The Dietary and Nutritional Survey of British Adults*, October 1986–August 1987	West German NVS, 1985–89	US CSFII, 1989–92 (detailed food codes within the following categories)
Breads	Bread	White bread Wholemeal bread Soft grain bread Other bread	Total bread	White bread Wholemeal bread Other bread	Knäckebrot Vollkornbrot und-brötchen Weissbrot sonstiges Brot	Yeast breads, rolls
Baked products	Biscuits and crispbread Cakes, buns and puddings	Biscuits Fruit pies Buns, cakes and pastries	Bran products Buns and pastries Cakes Biscuits	Biscuits Fruit pies Buns, cakes, and pastries	Kleingebäck Feingebäck, Dauerbackwaren	Cookies
Pastas	Pasta and rice	Pasta	Pasta	Pasta	Teigwaren	Pastas
Cereals	Breakfast cereals	Wholegrain and high fibre breakfast cereals Other breakfast cereals	Breakfast cereals	High fibre breakfast cereals Other breakfast cereals Other cereals	Weizenmehl und-griess Getreidekörner Erzeugnisse aus Getreide sonstige stärkehaltige Produkte	Cooked cereals Ready-to-eat cereals
Rice	(Accounted for in Pasta and rice category, as indicated above)	Rice	Rice	Rice	Reis	Rice

Table 8. Case Study Additive 2: additive use categories and corresponding food categories in survey data summaries.

Additive use categories	Food categories in survey data summaries					
	UK					
	Food and Nutrient Intakes of British Infants Aged 6–12 Months, 1986	*National Diet and Nutrition Survey: Children Aged $1\frac{1}{2}$–$4\frac{1}{2}$ years*, July 1992 and June 1993	*The Diets of British School Children*, 1983	*The Dietary and Nutritional Survey of British Adults*, October 1986–August 1987	West German NVS, 1985–89	US CSFII, 1989–92 (detailed food codes within the following categories)
Soft drinks	Squash and soft drinks	Diet soft drinks Other soft drinks	Colas Fizzy drinks Other soft drinks	Diet soft drinks Other soft drinks	Limonaden und sonstige Saftgetränke	Soft drinks
Biscuits	Biscuits and crispbread	Biscuits	Biscuits	Biscuits	Kleingebäck	Cookies
Confectionery	Chocolate confectionery Sugar confectionery	Sugar confectionery Chocolate confectionery	Chocolate Sweets	Sugar confectionery Chocolate confectionery	Schokolade Schokoladenerzeugnisse Zuckerwaren	Candies

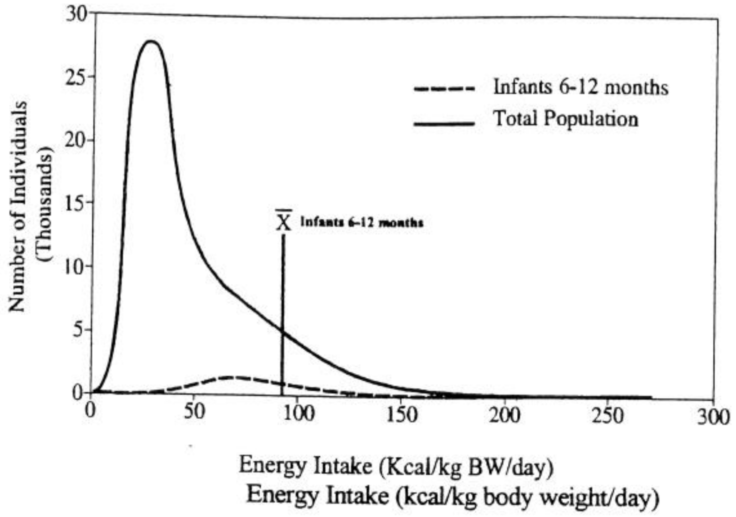

Figure 1. Mean daily energy intake distribution for the total population and for 1-year-olds, based on US survey data.

Table 9. Mean per capita *daily energy intake based on UK, West German and US survey data.*

Age group	Mean *per capita* energy intake (kcal/kg body weight/day)		
	UK	West Germany	US
Total population	NA	39[a]	35
6–12 months	96	NA[b]	91
$1\frac{1}{2}$–$4\frac{1}{2}$ years	76	NA	84[c]
10–11 years	44	59	50
14–15 years	49	44	36
16–64 years	34	35	26

[a] Ages 4+.
[b] NA, Not applicable (population group not included in survey).
[c] Ages 1–5 years.

Table 10. Energy density of food based on UK and US survey data.

Population	Energy density of food consumed, including milk products but excluding other beverages (kcal/g)
UK (ages 16–64)	1·63
US (total population	1·41

which is equivalent to two calories per gram. In contrast, UK and US survey data (table 10) indicate that the mix of food consumed, on average, is of slightly lower energy density (the collapsed German data used in this analysis did not permit calculation of energy density).

It appears that the Budget Method is based on an overestimate of energy density of foods consumed by the general population. Presumably, the extent of the overestimate would be even greater for sub-populations consuming large quantities of low calorie foods. However, the discrepancy between the energy density calculated here and that calculated by Hansen may be due to differing interpretations of what constitutes 'food' and what constitutes 'beverages'. For example, soup was considered a food in the present study, but may have not been considered so by Hansen.

Beverage and soft drink intake. Budget Method calculations for additive intakes from beverages are based upon the assumption that 100 ml/kg body weight of fluids, excluding milk, represents maximum consumption. The maximum soft drink consumption is assumed to be 25% of this consumption, or 25 ml/kg body weight/day.

Survey data on beverages are recorded in grams rather than millilitres, but can be compared in a general way if it is assumed that most beverages are as dense or denser than water, and have a density of 1 g/ml. Beverage consumption data are shown in table 11. It is likely that UK soft drink intakes by $1\frac{1}{2}$–$4\frac{1}{2}$-year-old children are higher than those by children of comparable ages in Germany and the US because water-diluted rose hip, blackcurrant, and other fruit cordials popular with young children in the UK are included in summarized soft drink intake data.

Table 11. Beverage and soft drink intake estimates based on UK, West German and US survey data.

	Mean *per capita* intake of non-milk beverages and of soft drinks (g/kg body weight/day)					
	UK		West Germany		US	
Age group	All non-milk beverages	Soft drinks only	All non-milk beverages	Soft drinks only	All non-milk beverages	Soft drinks only
Total population	NA[a]	NA	17[b]	2[b]	13	4
6–12 months	18	4	NA	NA	17	2
$1\frac{1}{2}$–$4\frac{1}{2}$ years	31	25[c]	NA	NA	18[d]	5[d]
10–11 years	8	4	16	5	11	5
14–15 years	9	3	13	4	11	6
16–64 years	23	2	18	2	13	4

[a] NA, Not applicable (population group not included in survey).
[b] Ages 4+.
[c] Water-diluted rose hip, blackcurrant, and other fruit cordials popular with young children in the UK are included in summarized soft drink intake data.
[d] Ages 1–5 years.

Table 12. Budget Method TMDI and survey-based intake estimates for Case Study Additives 1 and 2.

		Intake estimates based on food consumption survey data			
Food additive	Budget Method TMDI (mg/kg body weight)	Population	95th percentile *per capita* intake (mg/kg body weight/day)	Percent consuming foods containing additive	Percent total energy intake from foods containing additive (consumers)
1	0·63	UK[a]	0·34	90	33
		West German[b]	0·40	100	27
		US	0·43	99	25
2	15·00	UK	2·88	80	9
		West German	4·42	96	5
		US	5·12	78	8

[a] Ages 16–64: 95th percentile intake for this population computed as (mean intake × 3), as recommended by Bernier *et al.* (1994).
[b] Ages 4+.

Comparison of TMDIs with additive intake estimates based on food consumption survey data

Budget Method TMDIs calculated for Food Additives 1 and 2 (0·63 and 15·00 mg/kg body weight) are above the 95th percentile *per capita* estimates of intake for adults from all three surveys (table 12). However, in these case studies the proportion of the population consuming foods containing the additives is high (78–100%). If smaller proportions of the population were consuming foods containing the additive then *per capita* estimates of intake could under-estimate true levels of intake and the Budget Method would then be less conservative.

The Budget Method TMDI calculated for Food Additive 1 is within a factor of 2 of the survey 95th percentile values, indicating a close, yet still conservative estimate of intake. It is likely that no Type I or

Type II errors would occur in assignment of monitoring priority for Food Additive 1 using the Budget Method.

The scenario for Food Additive 2 is very different. The Budget Method TMDI for Food Additive 2 is 3–5 times the survey-based estimates of intake, indicating a potential for Type I (false positive) error in screening to establish monitoring priority.

Additives 1 and 2 are each used in a wide variety of foods, and a large proportion of the population consumes one or more foods in the contributing food groups. It is therefore difficult to evaluate the relative importance of factors contributing to differences in the extent to which Budget Method assessments might be useful for screening seemingly similar additives. Contributing factors may include relative energy contribution of solid foods containing the additives and relative volume contribution of beverages containing the additives.

Relative energy contributions of foods containing additives. Food Additive 1 is used in foods that contribute 25–33% of the total energy intake.The relative contribution of the foods in which Food Additive 2 may be used is much smaller, ranging from 5 to 9%. The Budget Method assumes that for solid foods, at least 25% of total food energy (using the factor of 160) and perhaps more often 50% of total food energy (using the factor of 80) will be contributed by foods containing the additive. The extent to which the Budget Method TMDI overestimates intake of additives present in foods contributing less than 25% of total energy compared with intake of additives contributing 25% of total energy or more should be tested in future studies.

Volume of liquids containing additives. The TMDI for Food Additive 2 is based on use in soft drinks as well as in solid foods. The assumption in the Budget Method is that soft drink consumption is 25 ml/kg body weight/day. However, as demonstrated in table 11, soft drink consumption is below the assumed level in each survey total population. The impact of the difference between Budget Method assumptions about soft drink consumption and actual population soft drink consumption on intakes of additives such as Food Additive 2 should be investigated further.

Conclusions

Budget Method assumptions regarding energy intake, energy density of foods, beverage consumption and soft drink consumption suggested the following conclusions:

- Assumptions regarding energy intake, beverage consumption and soft drink consumption of the general population are overestimates of actual average levels.
- The Budget Method assumption regarding energy density of foods may be an overestimate.

Budget Method TMDIs were in each of the two theoetical cases studied larger than survey-based *per capita* additive intake estimates for adults even when high-level intakes were considered. This analysis provides evidence that the Budget Method produces conservative estimates of average additive intakes over a lifetime. In fact, potential for Type I (false positive) errors in assignment of monitoring priority was observed in one of the case studies. The evidence provided is limited, but logic predicts that the method will tend to be conservative, and the potential for Type II (false negative) error is judged to be small.

Thus the Budget Method appears to be a conservative first screen for establishing priorities for monitoring consumption and use of food additives based on potential lifetime average exposures. The Budget Method may not be suitable for additives where there may be concerns about exposures over periods of less than a lifetime.

Acknowledgements

The authors gratefully acknowledge the support of the ILSI Europe Food Chemical Intakes Task Force.

References

BÄR, A., and WÜRTZEN, G., 1990, Assessing the use of additives in food: a reappraisal of the Danish Budget Method. *Lebensmittel-Wissenshaft und-Technologie*, **23**, 193–202.

Bernier, J. J., Causeret, J., Hoellinger, H., and Suschetet, M., 1994, Méthode pour assurer, au sein d'une population, le non-dépassement de la dose journalière admissible des additifs alimentaires. *Medicine et Nutricion*, **1**, 9–17.

Bingham, S. A., 1987, The dietary assessment of individuals: methods, accuracy, new techniques and recommendations. *Nutrition Abstracts and Reviews*, **57**, 705–742.

Black, A. E., Goldberg, G. R., Jebb, S. A., Livingstone, M. B. E., Cole, T. J., and Prentice, A. M., 1991, Critical evaluation of energy intake data using fundamental principles of energy physiology: 2. Evaluating the results of published surveys. *European Journal of Clinical Nutrition*, **45**, 583–599.

Black, A. E., Prentice, A. M., Goldberg, G. R., Jebb, S. A., Bingham, S. A., Livingstone, M. B. E., and Coward, W. A., 1993, Measurements of total energy expenditure provide insights into the validity of dietary measurements of energy intake. *Journal of the American Dietetic Association*, **93**, 575–579.

Briefel, R. R., McDowell, M. A., Alaimo, K., Caughman, C. R., Bischof, A. L., Carroll, M. D., and Johnson, C. L., 1995, Total energy intake of the US population: the third National Health and Nutrition Examination Survey, 1988–1991. *American Journal of Clinical Nutrition*, **62** (suppl), 1072S–1080S.

Hallas-Møller, T., 1987, Calculating possible daily intake to avoid exceeding the ADI. Paper presented at 'Food Additives—The Changing Climate?', First International Congress, Vienna, 5–7 February.

Hallas-Møller, T., 1995, Using the budget method as a quick screening method identifying food additives for which further monitoring is not warranted on health grounds. Draft report prepared for the SCF, 1 June.

Hansen, S. C., 1966, Acceptable daily intake of food additives and ceiling on levels of use. *Food and Cosmetics Toxicology*, **4**, 427–432.

Hansen, S. C., 1979, Conditions for use of food additives based on a budget for an acceptable daily intake. *Journal of Food Protection*, **42**, 429–432.

Haraldsdottir, J., 1993, Minimising error in the field: quality control in dietary surveys. *European Journal of Clinicial Nutrition*, **47** (suppl S2), 19-24.

National Food Agency of Denmark, 1986, *Danskernes Kostvaner 1985, 1*. Hovedresultater. Publikation nr. 136, November.

Nutriscan, 1994, Options for the routine collection of data on usage levels of food additives in the European Union. Final Report, December.

Schoeller, D. A., 1990, How accurate is self-reported dietary intake? *Nutrition Reviews*, **48**, 373–379.