An Evaluation of the Budget Method for Screening Food Additive Intake

Summary Report

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

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1. INTRODUCTION

The Budget Method is intended to provide a basis for a simple, inexpensive screening method for additive intake. It relies on assumptions regarding physiological requirements for energy and liquid and on energy density of food, rather than detailed information from food consumption surveys. The theoretical maximum daily intake (TMDI) is calculated by assuming that all foods contributing to energy intake, and all beverages contributing to liquid intake, will contain the additive at maximum permitted use levels. An additive is said to "pass" the Budget Method screen if the calculated TMDI is lower than the additive's corresponding acceptable daily intake (ADI).

Figure 1. Assumptions made in screening additive intake using the Budget Method: Additives used in food.

Maximum energy intake by young children consuming table foods is 100 kcal / kg body weight / day. Maximum energy intake over the course of a lifetime is 50 kcal / kg body weight / day. 50 kcal = 25 g food	25 g food = 1 / 40 kg food
The Theoretical Maximum Daily Intake (TMDI) of an additive can be calculated as:	*If:*
$\frac{\text{Maximum use level (mg additive / kg food)}}{40}$	The additive is used in foods other than baby foods and the maximum amount of food required to meet energy requirements is: $\frac{1/40 \text{ kg}}{\text{kg body weight}}$
$\frac{\text{Maximum use level (mg additive / kg food)}}{80}$	50% of foods consumed are processed foods.
$\frac{\text{Maximum use level (mg additive / kg food)}}{160}$	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).

An adaptation of the Budget Method developed by Søren Hansen (1966) of the National Food Agency of Denmark has been suggested as an appropriate screening method for determining priorities for monitoring the consumption and use of additives as required under European Union (EU) Directives 94/35/EC, 94/36/EC and 95/2/EC. Before it is accepted in the EU for such a purpose, however, the underlying assumptions should be examined to evaluate the potential for error in the use of results. Clearly, the Budget Method must minimise Type II (false negative) errors which could result in unchecked use of a substance that should have been a priority for monitoring. At the same time, Type I (false positive) errors should be as low as possible to prevent unnecessary expenditure of time and resources in pursuit of more detailed intake estimates.

This report summarises work performed by TAS (Technical Assessment Systems) International at the request of the International Life Sciences Institute - ILSI Europe Food Chemical Intake Task Force. The aim of the report was to evaluate the validity of assumptions on which the Budget Method is based and to assess the potential for Type I and II errors in using the method to establish additive monitoring priorities. The report should be read in conjunction with the references cited herein and listed at the end of this report.

Figure 2. Assumptions made in screening additive intake using the Budget Method: Additives used in beverages.

<table>
<tr><td colspan="2">Maximum intake of liquids (other than milk) is 100 ml/kg body weight/day.

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

2. BUDGET METHOD

The Budget Method was designed to compare food additive ADIs with "ceilings of use" calculated on the basis of maximum consumption 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 split into two fractions. The proportion of the ADI allocated to food and the proportion allocated to beverages are decided arbitrarily to accommodate technological requirements.

The proposal for use of the Budget Method calls for calculation of TMDIs using the assumptions outlined in Figures 1 and 2. Figure 1 describes the factors used and the assumptions made in estimating intake of additives from solid foods. Figure 2 describes the factors used and the assumptions made when estimating intake of additives from beverages.

3. METHODS

TAS International examined data from nationwide food consumption surveys conducted in the United Kingdom, former West Germany, and the United States (Figure 3). It examined whether Budget Method assumptions regarding energy intake, energy density of food and beverage soft drink consumption provide a valid basis for screening additive intake. Because the Budget Method assumes that ADIs for additives relate to average intake over a lifetime, the validity of assumptions was assessed on the basis of population averages rather than on high-level intake.

Because of limitations posed by the availability of European survey data, Budget Method assumptions regarding proportions of the diet accounted for by processed foods potentially containing additives could not be tested. The UK surveys were conducted on specific age groups, and results therefore were summarised on the basis of the UK age groups and on broad food groups.

4. CASE STUDIES

To evaluate the potential for Type I and II errors in using the Budget Method, case studies were conducted for two hypothetical food additives with different characteristics and proposed uses (Tables 1 and 2).

Table 1. Case Study of Additive 1: Used at similar levels in a broad range of foods consumed by a significant portion of the population.

Food Category	*Use limit (mg/kg food)*
Breads	50
Baked Products	50
Pastas	30
Cereals	50
Rice	30

Table 2. Case Study of Additive 2: Used in varying concentrations in a range of foods consumed by specific segments of the population.

Food Category	*Use limit (mg/kg food or mg/l beverage)*
Soft Drinks	350
Biscuits	1000
Confectionery	500

Maximum permitted use levels in specific food groups were selected to reflect typical use levels.

Food Additive 1 was designed to be representative of an additive used at similar levels in a broad range of foods

Figure 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 Ages 6–12 Months;* 1986; 488 infants; based on 7-day food intake records.
- *National Diet and Nutrition Survey: Children Ages 1.5–4.5 years;* July 1992 and June 1993; 1,675 children; based on 4-day food intake records.
- *The Diets of British School Children;* 1983; 3,581 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; 2,197 adults ages 16–64; 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 more than 25,000 individuals 4 years of age and older, using a system consisting of more than 6,000 food codes. Data used in the present analyses were taken from a dataset containing records of average daily intake 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 Intake by Individuals (CSFII). Together, the CSFII surveys measured dietary intake of more than 11,000 individuals over a 3-day period. Although these data clearly do not directly reflect European food intake patterns, it was believed that the extensive information on intake by individuals could be of potential value in examining basic Budget Method assumptions regarding food additive intake. 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 intake.

consumed by a significant proportion of the population. Food Additive 2 was designed to be representative of an additive used in varying concentrations in a range of foods consumed by specific segments of the population (e.g., an intense sweetener).

The Budget Method 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 (Figures 1 and 2).

Food consumption survey–based intake estimates for Additives 1 and 2 were calculated as precisely as possible given the limitations of the survey data. Additive use levels were applied to food consumption data in the categories shown in Tables 1 and 2.

Limitations on the availability of the survey data used in these analyses precluded calculation of per-user intake. However, it was assumed that all people will be consumers of the additives in question at some point in their lifetimes, and *per capita* estimates were therefore judged to be representative of lifetime intake. Because it is generally believed that the Budget Method generates conservative estimates of intake, TMDIs were compared with 95th percentile *per capita* intake. Where survey data did not permit assessment of 95th percentile *per capita* intake, the intake values were estimated using the Bernier method (Bernier et al. 1994) at three times the mean.

5. RESULTS

5.1 Energy intake

The survey results indicated 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 overestimate actual lifetime average energy intake by a small margin.

5.2 Energy density of food

In developing the Budget Method, Hansen (1966) assumed that 50 g of food have an energy value equal to 100 kcal, which is equivalent to 2 kcal/g. In contrast, UK and US survey data indicate that the mix of food consumed, on average, is of slightly lower energy density (the German data did not permit calculation of energy density).

The Budget Method is therefore based on an overestimate of energy density of foods consumed by the general population. The extent of the overestimate would be even greater for subpopulations consuming large quantities of low-calorie foods.

5.3 Beverage and soft drink consumption

Budget Method calculations for additive intake from beverages are based on the assumption that 100 ml/kg body weight of liquids, 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.

Beverage consumption data are shown for selected age groups in Table 3. In most cases these are clearly overestimated by the Budget Method assumptions. It is likely that UK soft drink consumption by 1.5–4.5-year-old children is higher than that by children of comparable ages in Germany and the USA because water-diluted rose hip, blackcurrant and other fruit cordials popular with young children in the UK are included in summarised soft drink consumption data.

5.4 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 all three national surveys investigated (Table 4), indicating that the budget method provides a conservative first estimate of intake.

It is unlikely that Type I or II errors would occur in the assignment of monitoring priority for additives like Food Additive 1 using the Budget Method. Additive 1 was intended to be representative of an additive used at similar levels in a broad range of foods consumed by a significant proportion of the population.

The scenario for additives like Food Additive 2 is different. This hypothetical additive was intended to be representative of an additive used in varying concentrations in a range of foods consumed by specific segments of the population (e.g., an intense sweetener). The Budget Method TMDI for Food Additive 2 is three to five times the survey-based estimates of intake, indicating a potential for Type I (false positive) errors. This means that the Budget Method is likely to falsely identify this type of additive as warranting further attention.

Table 3. Beverage and soft drink consumption estimates based on UK, West German and US survey data.

Age Group	*Mean Per Capita Intake of Non-Milk Beverages and of Soft Drinks (g/kg body weight/day)*					
	UK		West German		US	
	All non-milk beverages	Soft drinks only	All non-milk beverages	Soft drinks only	All non-milk beverages	Soft drinks only
Total population	NA[1]	NA	17[2]	2[2]	13	4
6 - 12 months	18	4	NA	NA	17	2
1.5–4.5 years	31	25[3]	NA	NA	18[4]	5[4]
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

(1) NA = not applicable (population group not included in survey).
(2) Ages 4+.
(3) Water-diluted rose hip, blackcurrant, and other fruit cordials popular with young children in the UK are included in summarised soft drink intake data.
(4) Ages 1–5 years.

Table 4. Budget Method TMDI and survey-based intake estimates for case study Additives 1 and 2.

Food Additive	*Budget Method TMDI (mg/kg body weight)*	*Intake Estimates Based on Food Consumption Survey Data*	
		Population	95th percentile *per capita* intake (mg/kg body weight/day)
1	0.63	UK[1]	0.34
		West German[2]	0.40
		US	0.43
2	15.00	UK	2.88
		West German	4.42
		US	5.12

(1) Ages 16–64; 95th percentile intake for this population computed as (mean intake x 3), as recommended by Bernier et al. (1994).
(2) Ages 4+.

6. CONCLUSIONS

The Budget Method assumptions regarding energy intake, energy density of foods, and beverage and soft drink consumption using UK, German and US national food consumption data were reviewed, and the following conclusions were reached:

- Assumptions regarding energy intake and beverage and soft drink consumption by the general population are overestimates of actual average levels. These probably add to the overall conservatism of the Budget Method.

- The Budget Method assumption regarding the energy density of foods may result in small overestimates. This probably detracts slightly from the overall conservatism of the method.

In the two case studies, Budget Method TMDIs were larger than survey-based *per capita* additive intake estimates, providing evidence that the Budget Method produces overestimates of additive intake. The potential for Type II (false negative) errors is therefore judged to be small whereas the potential for Type I (false positive) errors seems to be relatively large.

Thus, the Budget Method appears to be a satisfactory conservative first screen for establishing priorities for monitoring the intake of food additives, based on potential average lifetime food consumption.

7. REFERENCES

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