Conditions for Use of Food Additives Based on a Budget for an Acceptable Daily Intake

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ABSTRACT

Use of food additives is regulated qualitatively in the European Common Market through the EEC directives on food additives, while the concept of Acceptable Daily Intake (ADI) provides a quantitative expression of safe amounts for the guidance of regulatory agencies. It is suggested that a permissible quantity or quantities, the ceiling, should be agreed upon for each permitted additive on the basis of its ADI and in accordance with the procedure described here. The estimation of intake of food and drink starts from the child, who on the basis of body weight has the highest consumption. When dealing with total intake (expressed as energy, weight or volume per kg body weight per day), occupational and climatic variations between adults are largely contained in the difference between child and adult. It is possible to calculate the highest concentration in foodstuffs which is consistent with the ADI, under the assumption that the additive occurs evenly distributed in the whole diet of a child. This concentration is called the primary ceiling. To obtain the technological effect, however, higher concentrations may be needed, and to accommodate this the ceiling may have to be raised. This can be done if the use of the additive can be excluded from or reserved for part of the diet.

The method described here has its origin in talks 20 years ago with people interested in the fluoridation of drinking water. It was in a way fascinating that 1 mg of fluoride per liter of water gave optimal inhibition of dental caries, while 0.5 mg gave very little protection in a population, and 2 mg was causing slight mottled enamel of the teeth in some individuals. How is it possible with the ADI, under the assumption that the additive occurs evenly distributed in the whole diet of a child. This concentration is called the primary ceiling. To obtain the technological effect, however, higher concentrations may be needed, and to accommodate this the ceiling may have to be raised. This can be done if the use of the additive can be excluded from or reserved for part of the diet.

Many other toxic substances occur naturally in foods and beverages, often in amounts such that the margin of safety is rather small. The normal solanine content of potatoes is safe irrespective of eating habits, simply because satiety is reached before a toxic amount is consumed. Potatoes are safe food in Ireland and more so in countries where they are not the staple starchy food. Alcoholic beverages are classed as toxicants, and are taxable if they contain more than 2% ethanol, but levels below that are considered safe. An idea which immediately suggests itself is that thirst is the controlling factor for fluoride and ethanol, the degree of dilution of the toxic substance restricting its intake and being decisive for safety. Similarly the intake of energy-giving foodstuffs and accompanying substances is controlled by appetite.

As is shown below, our knowledge about the physiological quantities, liquid and energy intake, can be used to limit the intake of food additives to amounts considered acceptable by the toxicologists. This procedure may at first sight look unduly restrictive because of the great variety of eating habits and patterns of consumption: An Eskimo selects his diet differently than does a Mediterranean peasant. But nevertheless the nutritionists' message about too high a fat, sugar, and alcohol consumption, and their recommendation to increase the cereal consumption has a general address. This leads to the belief that there are many similarities, and these should of course receive primary consideration when conditions of use of food additives are being defined.

Let us take fat consumption and use of antioxidants as examples. A legal provision that relates the permissible level of antioxidants to the fat content of the food commodity in question may aim at toxicological protection of the high-fat consumers with 50% of their energy intake from fat, the average-fat consumers with 40% from fat, or the optimal-fat consumers with only 30% from fat, but such small differences are of minor importance and could be disregarded when dealing with relatively non-toxic substances like food additives. That an antioxidant is at first being proposed for preservation of, e.g., lard only should not lead to legal provisions and limitations of use based on average lard consumption figures because such consumption varies considerably. The lard consumption will probably increase in some part of the population due to the use of the antioxidant, but the percentages for fat energy given above still hold true.

ACCEPTABLE DAILY INTAKE (ADI)

The Joint FAO/WHO Expert Committee on Food Additives (6,9) has introduced the concept of zones of acceptable daily intake (ADI) of food additives and applied the concept to compounds under appraisal. The ADI of an additive is established from the results of prolonged feeding experiments with animals. (Some toxicological quarters are now considering the Weekly Intake as more appropriate than the Daily Intake). From

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the level of intake that produces no effect the ADI for man is estimated by application of a safety factor and expressed in milligrams per kilogram of body weight per day:

\[
\begin{align*}
\text{No effect level in animals} & \quad \rightarrow \quad \text{ADI for man} \\
100 \text{ mg/kg b.w./d.} & \quad \rightarrow \quad a \text{ mg/kg b.w./d.}
\end{align*}
\]

First to be discussed in the following is how knowledge about liquid and food (energy) intake can be used to insure that ADI is not being exceeded.

**Intake of beverages**

Fig. 1 shows the correlation between the recommended daily intake (4) of liquid and age, when the liquid intake is presented on the basis of body weight. It shows a prominent steep decline during the earliest period of life. There is, of course, a certain variation in liquid intake, but for our purpose we need only be concerned with the variation in high intake. 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. A 60-kg man is protected even if he drinks up to 6 liters per day which meets his requirement under extreme working conditions (1).

**Intake of food (energy)**

Man needs both drink and food, and food means energy. The next figure (Fig. 2) is drawn up in a similar way as the first one. It shows the correlation between the recommended daily intake (4) of energy and age. The energy requirement is presented on the basis of body weight and we note again the 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.

The daily energy intake of children per unit of body weight exceeds that of adults. Under very heavy conditions of work, such as those of Canadian lumberjacks, intakes of 60-70 kcal/kg of body weight per day have been recorded (1).

Food is eaten largely to satisfy energy requirements. To achieve and maintain proper weight for age, the amount of food consumed over a period must reflect energy needs fairly precisely. For no age group, when energy requirements are met, may the foods contain more of an additive than ADI (a mg/kg b.w./d.). For balance, energy intake and the ADI of additives are expressed on the basis of body weight.

How much is 100 kcal (Fig. 3)? It depends on the food we are talking about. For butter and margarine 100 kcal corresponds to 12 g, for sugar it is 25 g and for average food including milk but excluding other beverages, it corresponds to 50 g.

In this context, bulk and the energy density of the food are important. Fruit by itself is not a satisfying food in the sense that it does not readily produce a feeling of satiety, but with sugar and whipped cream it is. New products such as low-fat margarine and mayonnaise, low-sugar marmalade, semi-dried plums, and other semi-moist foods, are readily accepted because they are not too heavy and not too watery. Such foods fit into a dietary...
WEIGHT OF 400 KJ (100 KCAL):

50 GRAMS OF AVERAGE FOOD, OR

25 GRAMS OF SUGAR, OR

12 GRAMS OF MARGARINE OR BUTTER

Figure 3. One hundred kcal are provided by different amounts of food.

pattern with an energy kcal value of about 400 KJ (kcal) per 50 g.

If a child 1 year of age is used as a reference subject, the ADI is not exceeded if 50 g of food equivalent to 400 KJ does not contain more than the ADI (a mg). Except for very low-energy foods, a mg of an additive can always be allowed in 50 g of food, i.e., 20 a mg/kg (20 a ppm). That is the primary ceiling on the level of use of the additive.

SAFETY MARGIN ALLOWS A FACTOR OF 2

(2 X 20 a = 40 a ppm)

The ceiling of 20 a ppm is based on premises different from those on which the ADI is established (6). The 100-fold safety margin is meant to cover, among other things, the difference between children and adults and the variation in food intake among adults. Fig. 2 shows that these variations are largely circumvented in the present approach. It is therefore taken for granted that, except for baby foods, a factor of 2 can be allowed, hence the primary ceiling of 20 a can be raised to 40 a ppm.

NEW FOOD PRODUCTS AND ADDITIVES

It is generally agreed that an additive should be permitted only when it is needed, and that the amount used should be in accord with good manufacturing practice. Furthermore, if the health authorities would indicate the ceiling to which each additive could be used without endangering public health, the industry would be free to develop new food products within this framework. New products (Fig. 4) might become popular and ingested in substantial amounts, but as the intake of additives would be controlled by appetite and thirst we and our children may eat and drink according to custom, ingesting additives in any amounts up to the ADI. The system is named a budget for ADI, because new products can always be accepted within the ceiling.

The EEC directives on food additives at present contain lists with names of permitted chemicals. Such qualitative rules will need to be worked out with rules for the permitted quantities of each additive. Experience within the EEC framework shows that the horizontal approach (i.e. general rules for all foodstuffs) has advantages over the vertical approach (i.e. specific directives for the various foodstuffs). The horizontal approach can be maintained after setting permitted quantities only if the ADI is budgeted for. The horizontal approach becomes possible if the ceiling is not lower than the technologically effective level. If a full horizon (i.e. that the additive may in principle occur in all foodstuffs) demands too low a ceiling, the additive may be permitted in part of the diet, e.g., in half or a quarter of the horizon. Variations less than 2-fold are not considered.

RESERVED OR EXCLUDED USES OF FOOD ADDITIVES

National food balance sheets prepared by the FAO (3) have shown that the diet becomes adjusted to the gross national product by changes in the proportion of energy derived from various sources. Other investigations have shown that in affluent countries the contributions of various food groups to the energy intake of the people are as follows.

- Cereals show a downward trend toward 25%
- Fat, total, tends to move upward, approaching 50%
- Fat, visible, is almost constant at 18%
- Meat, fish and eggs are approaching 25%
- Milk and other dairy products are almost constant at 10-13%
- Sugar is moving slowly upward from about 16-18%

If a fully horizontal approach is not possible, the budget should be based on bread groups of foodstuffs akin to the dietary elements (fat, sugar, protein, complex carbohydrate) used in nutritional considerations. On this point, the ADI-budget is at variance with the plan originally suggested from toxicological quarters (6) who foresaw detailed food consumption surveys and “bookkeeping” on that basis.

ESTIMATED HIGH INTAKE OF CATEGORIES OF BEVERAGES

It is also possible to select categories of beverages which are not likely to be the only beverage in a high consumption situation. Figure 5 presents three alternatives. The first alternative is the fully horizontal...
approach, which assumes an intake of 100 ml/kg b.w./d., and which with an ADI of \( a \) mg/kg b.w./d. leads to a ceiling of 10 \( a \) mg per liter, protecting both child and adult. The second alternative foresees a high intake of 50 ml and the third alternative assumes that high intake is only 25 ml/kg b.w./d. If the technological requirement cannot be met under the first alternative, consideration must be given to the next alternative, which allows a doubling of the ceiling, or to the third alternative which allows a redoubling.

Figure 6 contains suggestions as to high intake figures for beer, wine and soft drinks. It should be noted that because of competition in the intake pattern such high intake figures are not additive. If the same substance is of interest in all three categories of beverages 50 ml/kg b.w./d., and not 100, should be used for the calculation. In making the choice between these three alternatives (and no further alternatives seem possible), both judgement and data on beverage consumption should be used. For a man weighing 60 kg, the estimated intake of beer is 3 liters which seems to give reasonable protection.

**Half the liquid intake is represented by:**

A

1) beer

**One quarter of the liquid intake is represented by:**

B

1) wine
2) soft drink

Figure 6. *Values for a high intake of beer, wine, and soft drinks.*

**ESTIMATED HIGH INTAKE OF FOOD CATEGORIES**

Figure 7 presents three alternatives: 50 g, 25 g and 12 g/kg b.w./d. If the door should be kept open for a technologically promising new additive to be used in a great variety of foodstuffs, it may be wise to pick the first and most cautious alternative. The ceiling is doubled and redoubled in alternatives 2 and 3.

The shade of two adults in Fig. 7 is to remind that there are good reasons to believe that the toxicologists have included the difference between child and adult in the safety margin when they established the ADI. We are therefore unduly cautious, when we base our calculations on the intake of a one-year-old child. A factor of 2 should be permissible.

If 40 \( a \) mg/kg foodstuff is below the technologically necessary level, an early decision has to made as to what food items should be excluded from the use of the additive, or for which foodstuffs use should be reserved. Figure 8 offers suggestions as to the selection of the most appropriate of the three alternatives for some characteristic components in our diet.

Cereals (or better, starchy foods) make up the main part of the diet in poor countries, but all parts of the world some people eat a substantial amount of bread, potatoes, pizza and pasta. Some years ago a Dutch survey (7) showed that teen-agers going to school by train might get as much as 70% of their energy intake by eating bread. Seventy percent of a teen-ager’s intake corresponds to 50 kcal (or 22 g of bread)/kg b.w./d. If, e.g., potato flakes for preparation of mashed potatoes need a certain additive it may be wise to foresee that the same additive will be useful in other kinds of flaked and powdered starchy convenience foods, even in bread-mixes.

The second alternative, 25 g/kg b.w./d., may also be chosen if the food additive in question can be excluded from fresh food, cereal and dairy products.

The third alternative should be considered in the six options listed in Fig. 8. These groups of foodstuffs
Half the energy intake is represented by:

1) CEREALS
2) TOTAL FAT
3) OTHER THAN FRESH FOOD, BREAD AND DAIRY PRODUCTS.

One quarter of the energy intake is represented by:

1) DAIRY PRODUCTS - OTHER THAN MILK
2) VISIBLE FAT
3) SUGAR
4) MEAT, FISH, POULTRY AND EGGS
5) PASTRY AND BREAKFAST CEREALS
6) OTHER THAN FRESH FOODS, BREAD, DAIRY PRODUCTS AND VISIBLE FAT.

Figure 8. Alternatives that may be chosen from characteristic components of our diet.

Compete for room in the diet as a whole and hence are not additive, but four of the groups together make up a high intake of 25 g/kg b.w./d.

ALLOCATIONS OF ADI TO FOODSTUFFS AND BEVERAGES

If a particular additive is used in both solid foodstuffs and beverages, the ADI must be split into two fractions and the size of each must be decided upon arbitrarily to accommodate the technological requirements as far as possible. (See the example with benzoic acid below). If the ADI is too low to meet both requirements, an administrative decision is necessary so that one additive may be reserved for use in solid foodstuffs and another with the same technological effects for use in beverages.

EXPERIENCE WITH THE BUDGET APPROACH IN DENMARK

In 1973 the Danish administration was instructed to draft a list of permitted food additives (2) in accord with the acceptable daily intake values established by WHO. Data on actual intakes were not available and there was no detailed information on the dietary pattern. Information about potential uses and levels of use in different foods was taken from food standards of the Codex Alimentarius, industry, the literature and other sources. The findings were presented in data sheets, one for each additive (Fig. 9). It was realized that the information was not complete, that the sheets would require continuous updating and that future developments would necessarily be added. For some additives there were only a few uses, and others were used in a wide variety of foodstuffs.

Benzoic acid (Fig. 9) is a well-known and often used preservative used in foodstuffs. The food industry suggested as permitted levels the figures shown in the first column. Margarine is not on the list, but benzoic acid has in fact been used in margarine in some parts of the world. Most of the figures were quoted from earlier legislation where also the so-called percentage rule applied (see below). The primary ceiling 20 $\times $ ( = 200 ppm) was uninteresting from a technological point of view. To reach technologically effective levels, a factor of 80 or 160 should be used. To remain within the ADI, only one-quarter of the foods and one-quarter of the beverages consumed by a child may contain this additive. It was decided administratively to exclude the use of benzoic acid in milk and meat and their products, bread and visible fat (except mayonnaise). This limited its use so much that the third alternative could apply (the estimated high intake was 12 g of food/kg b.w./d.), and the factor 160 was used. Soft drinks etc. required a special allocation from the ADI and the factor 40 was used.

At that time, in 1973, there was a conditional ADI of 10 mg/kg b.w./d. for benzoic acid (6); today, however the ADI is only 5 mg/kg b.w./d., as WHO (9) has withdrawn all conditional ADI's. It is therefore questionable, whether there will be an allocation at all for beverages (or other foodstuffs).

The levels finally accepted for benzoic acid are a little higher than those calculated (Fig. 9, second column).

PERCENTAGE RULE ABOLISHED

In earlier legislation in Denmark, a rule governing use of mixtures of food additives stated that if the amount of each additive is expressed as a percentage of the maximum amount permitted, the sum should not exceed 100. This rule was abolished except for cases in which the ADI is expressed as a sum of a number of related additives. Abolition of the percentage rule was considered to be essential for estimation of the intake. The rule had forced the authorities to set permissible levels rather high.

Data sheet for benzoic acid

<table>
<thead>
<tr>
<th>Additive</th>
<th>Suggested level ppm</th>
<th>Accepted level ppm</th>
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</thead>
<tbody>
<tr>
<td>Mayonnaise</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Mayonnaise, low-fat</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Semi-preserved fish and fish products</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Fish and fish products in brine</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Tomato paste and ketchup</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Potted fruits and vegetables</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Meat products</td>
<td>2000</td>
<td>0</td>
</tr>
<tr>
<td>Mustard</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Worcestershire sauce</td>
<td>2000</td>
<td>2000</td>
</tr>
<tr>
<td>Marmalade, jam</td>
<td>1000</td>
<td>500</td>
</tr>
<tr>
<td>Juice, lemonade, etc.</td>
<td>250</td>
<td>500</td>
</tr>
<tr>
<td>Confectionary</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Cakes and fine bakery'seware</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>Salad and dressings</td>
<td>2000</td>
<td>1000</td>
</tr>
<tr>
<td>Non-standardized foodstuffs</td>
<td>2000</td>
<td>500</td>
</tr>
</tbody>
</table>

CEILING FOR FOODSTUFFS:

160 x 5 = 800 mg benzoic acid/kg food

ADI = 10 mg/kg b.w./d. (conditional ADI).

CEILING FOR BEVERAGES:

40 x 5 = 200 mg benzoic acid/litre.

Figure 9. Data sheet for benzoic acid.
in older legislation, e.g., 2000 ppm for benzoic acid. Lower figures in new legislation may not necessarily mean stricter rules.

**DISCUSSION**

National governments and international organizations have already laid down quantitative food additive provisions in food standards. This principle of "first come, first served" that is at present applied in food standardization will eventually conflict with the principle of the ADI because new food products will demand their share of the ADI. New products can probably not be accepted because of a too liberal policy in the past, and because traditional types of foodstuffs have been given ADI-allocations in accordance with eating habits in former times. ADI budgets should therefore be agreed upon and ceilings established for inclusion in horizontal food additives directives.

The main objection to the budget is that the ceilings are unnecessarily low, that they leave too much accommodation for future development and, therefore, are "extra safe." But the alternative, detailed surveys of food consumption, may lead to even lower permissible levels because many high intake figures from such surveys may result in an unrealistically high total. In the philosophy of the budget, however, it is recognized that no one individual can be a high consumer of everything.

The ADI-budget should be considered an adjunct to food consumption surveys in a similar way as budgeting and book-keeping are parallel operations in finance.

The budget is based on broad groups of foodstuffs akin to the dietary elements (fat, sugar, protein, complex carbohydrate) used in nutritional considerations. On this point the ADI-budget is at variance with the plan originally suggested from toxicological quarters who foresaw detailed food consumption surveys and "book-keeping" on that basis.

In the presentation of the budget, it is assumed that certain variations less than 2-fold can be absorbed by the safety margin, but it is debatable whether this is an unduly cautious position. Very few toxicologists (Danish and Swedish) have yet had experience with the budget, and as long as there is no general agreement as to the acceptable variation in food intake it is not meaningful to discuss actual figures. The budget for benzoic acid should therefore be looked at as an illustration. Generally, the budget is not meant to be a dietation, but should be considered for use as a tool in a future dialogue between toxicologists and food technologists (5).

Instead of leaving the initiative with the toxicologists, the food technologists might suggest a ceiling on the level of use and ask for toxicological clearance of the corresponding daily intake. This could facilitate the task of the toxicologists. If then the budget is administered in cooperation with toxicologists and food technologists, it might facilitate progress in this important field.

**REFERENCES**