Technical review of EFSA Food Additive Intake Method (FAIM)

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Technical review of EFSA Food Additive Intake Method (FAIM)

Introduction

Background

At the Workshop on the new Guidance for Submission for food additive evaluations which The European Food Safety Authority (EFSA) hosted on September 21 in Brussels, the Food Additives Intake Model (FAIM) template was introduced to industry stakeholders and a period of consultation was announced. The FAIM template and instructions for its use were circulated to stakeholders on 5th October with a deadline for submissions of comments of 26th October. The deadline was later extended to 2nd November 2012 allowing four weeks for industry experts to review the method and collate their comments.

In response to the consultation, industry organisations that had attended the September Stakeholder meeting agreed to sponsor a technical review of the FAIM method in order to help understand better its data, methods of working, underlying assumptions and possible consequences of its use. David Tennant at Food Chemical Risk Analysis was commissioned to undertake this review in time to support the provision of comments to EFSA by 2nd November.

Approach

Given the very short time frame 5 key tasks were identified:

1 Assess the food categories used in the FAIM in comparison with the full categorisation available within the full EFSA FOODEX categorisation system (Levels L1 to L4) and against the food additive usage categories listed in Commission Regulation (EU) No 1129/2011.

2 Consider additional usage categories in the EFSA FOODEX system that could be relevant to the specific uses of food additives identified in FDE usage surveys by providing an additional break-out of Regulation (EU) No 1129/2011 categories. Recommend suitable food categorisation system for food additives exposure modelling system.

3 Evaluate the food consumption data provided in the FAIM by estimating energy intakes associated with each food type using international food composition data and comparing average and 95th percentiles from each food category and total energy intake from all foods combined with WHO nutrient requirements guidelines for each age group.

4 Evaluate the total exposure calculation method used in FAIM and compare results with alternative approaches that take 'typical' usage into consideration alongside maximum levels. In particular a spread sheet model initially developed for screening exposures to food colours and the FACET system. Analyse uncertainties associated with each method.

5 Assess status of the FAIM model in a tiered approach to exposure assessment and evaluate the degree of conservatism associated with its use. Approaches to be evaluated would include (1) initial ANS assessment, (2) FAIM model, (3) alternative 'colours model' and (4) FACET. Incorporate usage data from recent EFSA evaluations to illustrate comparisons.

Each of the above tasks is reported in Sections 1 to 5 of this report.

The tasks were undertaken in consultation with food industry experts to ensure that the best available information on current patterns of use of food additives in Europe was reflected in the report

Results and conclusions

Results are described in each section of the report and conclusions drawn together in a separate section at the end. It is important to note that the results and conclusions can be regarded as provisional only because of the very limited time made available to undertake this study.

Declaration of interest

This work was sponsored and funded by food additive producer and user organisations:

FoodDrinkEurope, ELC (specialty food ingredient producers in Europe), NATCOL (the Natural Colours Association), CEFIC (the European Chemical Industry Council), EUTECA (the European Technical Caramel Association) and UNESDA (the European non-alcoholic beverages association).

Technical review of EFSA Food Additive Intake Method (FAIM)

Section 1 – Food classification

Aim:

Assess the food categories used in the FAIM in comparison with the full categorisation available within the full EFSA FoodEx categorisation system (Levels L1 to L4) and against the food additive usage categories listed in Commission Regulation (EU) No 1129/2011.

Background

Food categories included in the FAIM model are based on the European Commission's classification system used for food additives as set out in Commission Regulation (EU) No 1129/2011[1]. They are drawn from the available FoodEx categories used to organise the data in the EFSA Comprehensive European Food Consumption Database[2]. The FoodEx categorisation system has 20 broad classes broken down into nearly 2,000 sub-categories at four different levels of detail. In the FAIM model there are 19 broad classes broken out into 47 sub-groups. This is in contrast to the Commission's additives classification scheme which has 22 broad classes broken out into 136 sub-groups[3].

This means that there are some limitations on the correspondence between the categories used for regulating food additives, the categories in the FoodEx system and the system used in FAIM. One of the aims of the FAIM system is to provide a simple approach to dietary exposure modelling and so it is expected that the number of food categories will therefore have been set at the minimum. There is a further consideration that the method used to estimate high level exposure (highest 95th percentile from one food plus mean from other foods) is valid only when the number of food groups is limited. There is therefore a necessary trade-off between simplicity and accuracy. The nomenclature used in FAIM is summarised in Table 1.1.

The FAIM instructions for use note that some food groups have many sub-groups below level 2 of the Regulation 1129/2011 Food Classification System, such as fruits and vegetables, meat, and alcoholic beverages food groups. However, instead of provided more detailed classification so the users can select those that are relevant to the additive, the model recommends that the highest values should be inserted in the template to perform the exposure calculation, except when the product on which the highest level applies is a very specific product. The effect of this assumption requires full evaluation.

[1] Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295/1, 12.11.2011.

[2] http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

[3] https://webgate.ec.europa.eu/sanco_foods/main/?sector=FAD&auth=SANCAS

Table 1.1. Categorisation system used in FAIM

	Nomenclature used in the FAIM template		
FCS Level 1	FCS name Level 1	FCS Level 2	FCS name Level 2
1	Dairy products and analogues	1.1	Unflavoured pasteurised and sterilised (including UHT) milk
1	Dairy products and analogues	1.23	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)
1	Dairy products and analogues	1.4	Flavoured fermented milk products including heat treated products
1	Dairy products and analogues	1.5	Dehydrated milk as defined by Directive 2001/114/EC
1	Dairy products and analogues	1.6	Cream
1	Dairy products and analogues	1.7.1	Unripened cheese excl. products falling in cat. 16
1	Dairy products and analogues	1.7.2	Ripened cheese
1	Dairy products and analogues	1.7.4	Whey cheese
1	Dairy products and analogues	1.7.5	Processed cheese
1	Dairy products and analogues	1.8	Dairy analogues, including beverage whiteners
2	Fats and oils, and fat emulsions	2.1	Fats and oils essentially free from water (excluding anhydrous milkfat)
2	Fats and oils, and fat emulsions	2.2	Fat and oil emulsions mainly of type water-in-oil
3	Edible ices	3	Edible ices
4	Fruit and vegetables	4.1	Unprocessed fruit and vegetables
4	Fruit and vegetables	4.2	Processed fruit and vegetables
5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC
5.2	Other confectionery including breath refreshening microsweets	5.2.1	Other confectionery with added sugar
5.2	Other confectionery including breath refreshening microsweets	5.2.2	Other confectionery without added sugar
5.3	Chewing gum	5.3.1	Chewing gum with added sugar
5.3	Chewing gum	5.3.2	Chewing gum without added sugar
6	Cereals and cereal products	6.1	Whole, broken, or flaked grain
6	Cereals and cereal products	6.2	Flours and starches
6	Cereals and cereal products	6.3	Breakfast cereals
6	Cereals and cereal products	6.4	Pasta
6	Cereals and cereal products	6.5	Noodles
7	Bakery wares	7.1	Bread and rolls
7	Bakery wares	7.2	Fine bakery wares
8	Meat	8.1	Unprocessed meat
8	Meat	8.2	Processed meat
9	Fish and fisheries products	9.1.1	Unprocessed fish
9	Fish and fisheries products	9.1.2	Unprocessed crustaceans and molluscs
9	Fish and fisheries products	9.2	Processed fish and fishery products including mollusks and crustaceans
9	Fish and fisheries products	9.3	Fish roe
10	Eggs and egg products	10.1	Unprocessed eggs
10	Eggs and egg products	10.2	Processed eggs and egg products
11	Sugars, syrups, honey and table-top sweeteners	11.1	Sugars and syrups as defined by Directive 2001/111/EC
11	Sugars, syrups, honey and table-top sweeteners	11.2	Other sugars and syrups
11	Sugars, syrups, honey and table-top sweeteners	11.3	Honey as defined in Directive 2001/110/EC
11	Sugars, syrups, honey and table-top sweeteners	11.4	Table Top Sweeteners
12	Salts, spices, soups, sauces, salads and protein products	12.1	Salt and salt substitutes
12	Salts, spices, soups, sauces, salads and protein products	12.2	Herbs, spices, seasonings
12	Salts, spices, soups, sauces, salads and protein products	12.3	Vinegars
12	Salts, spices, soups, sauces, salads and protein products	12.4	Mustard
12	Salts, spices, soups, sauces, salads and protein products	12.5	Soups and broths
12	Salts, spices, soups, sauces, salads and protein products	12.6	Sauces
12	Salts, spices, soups, sauces, salads and protein products	12.7	Salads and savoury based sandwich spreads
12	Salts, spices, soups, sauces, salads and protein products	12.8	Yeast and yeast products
12	Salts, spices, soups, sauces, salads and protein products	12.9	Protein products, excluding products covered in category 1.8
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC	13.1	Foods for infants and young children
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC	13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC	13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC	13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) 41/2009[4]
14.1	Non-alcoholic beverages	14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
14.1	Non-alcoholic beverages	14.1.2.1	Fruit juices as defined by Council Directive 2001/112/EC
14.1	Non-alcoholic beverages	14.1.2.2	Vegetable juices
14.1	Non-alcoholic beverages	14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products
14.1	Non-alcoholic beverages	14.1.4.1	Flavoured drinks with sugar
14.1	Non-alcoholic beverages	14.1.4.2	Flavoured drinks with sweeteners
14.1	Non-alcoholic beverages	14.1.5	Coffee, tea, , herbal and fruit infusions, chicory, tea; tea, herbal and fruit infusions, and chicory extracts; tea, plant, fruit and ...
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts
15	Ready-to-eat savouries and snacks	15.1	Potato-, cereal-, flour- or starch-based snacks
15	Ready-to-eat savouries and snacks	15.2	Processed nuts
16	Desserts excluding products covered in category 1, 3 and 4	16	Desserts excluding products covered in category 1, 3 and 4
17	Food supplements as defined in Directive 2002/46/EC[5] excluding food supplements for infants and young children	17	Food supplements as defined in Directive 2002/46/EC[5] excluding food supplements for infants and young children
18	Processed foods not covered by categories 1 to 17	18	Processed foods not covered by categories 1 to 17
99	Unclassified foods	99	Unclassified foods

The FoodEx categories associated with each of the categories in the FAIM model are also provided in the system ('Foods list' tab) and so it is possible to see which FoodEx categories have been assigned to each FAIM group. The categorisation system has been circulated among industry experts to seek views on the degree to which the FAIM classification meets the requirements for food additive exposure assessments and the relevance of FoodEx categories to each additive application. However, because of the limited time available for this consultation this process has not been exhaustive and the conclusions of this section should be regarded as indications only.

Recommendations

Industry experts broadly concurred with the categorisation approach because it partly coincides with the Regulation 1129/2011 system. The separation of 'other confectionery', 'flavoured drinks' and 'chewing gum' into with and without sugar was welcomed because it will be useful when evaluating artificial sweeteners. However, sweeteners may also be used in other foods that contribute significantly to exposures, in particular 'Desserts' and 'Ices' and so further sub-division of these categories is also necessary.

Industry experts identified several omissions in the food categorisation system that could lead to significant inaccuracies in the model. For example, the provision of just one category to represent 'Alcoholic beverages' will lead to significant errors. This is because alcoholic drinks vary very widely in both composition and amounts consumed. The extremes of the variation can be represented by beers and spirits. An additive that is required in low concentrations in beer-like drinks may be required at very different concentrations in pure spirits. However, the volume of beer consumed is much greater that the volumes of spirits consumed. As a consequence, if the maximum use level for an additive in alcoholic drinks was associated with spirits or another drink consumed in small amounts, then the FAIM model would apply this to all alcoholic beverages including beers that are consumed in large amounts by some consumers. This would result in significant over-estimation of intakes from this source.

Sauces provides an example of mixing of categories, the consumption of which are not comparable, i.e. ready-to-eat, dehydrated and concentrated products; chili sauces, ketchup and chutneys are consumed in very small amounts. However, food consumption data for sauces at the 95th percentile from the Comprehensive system are rather high (up to 87 g/day for children, 173 g/day for adolescents and 137 g/day for adults (up to 3.7 g/kg bw/day for children). It is suggested to subdivide this category into 12.6.1 'Savoury sauces other than ketchups and condiments' and 12.6.2 'Ketchups, condiments' and 12.6.3 'dried/concentrated sauces'.

Other areas where categories are missing that require different use levels include:

- Dairy products. It was suggested that this should include the sub-category 'other cheese products'.
- Processed fruit and vegetables. This requires sub-division into dried fruit and vegetable, canned and bottled products (consumed in relatively large amounts) and compotes, jams and preserves (consumed in small amounts). Processed potato products should also be separated. Dried fruits are of particular importance

because they may include relatively high levels of certain additives but are consumed in very small amounts.

- Confectionery. Confectionery is a broad food category for which sub-categorisation is important for an intake assessment exercise (for instance, high levels of certain colours can be added to filings and coatings and not to the whole confectionery product). Ideally, 'Decorations and coatings' should be available as a usage category to avoid over-estimation. Because the category does not exist in the FoodEx system, it should be made clear that when additives are used in this way the use levels cannot be included in the FAIM model.
- Fine bakery wares. The method should separate cereal bars, pastries and cakes and biscuits (cookies) to allow for variations in use levels. Comments about 'Decorations and coatings; also applies.
- Unprocessed meat. Include only breakfast sausages, burger meat, *gehakt* and pre-packed preparations of fresh minced meat (other colour use limited to health marking).
- Processed meat. Separate sub-categories are required for heat-treated meat, patés and terrines and cured meat products to allow for variations in use levels.
- Sauces. Sub-divided into 12.6.1 'Savoury sauces other than ketchups and condiments' and 12.6.2 'Ketchups, condiments' and 12.6.3 'dried/concentrated sauces'.
- Non-alcoholic beverages. Use all Foodex categories (containing fruit, flavoured, colas, etc.) because additive use is linked to flavour, etc.
- Non-alcoholic beverages. Include milk-based drinks as a separate category because use levels are different from water-based drinks.
- Non-alcoholic beverages. Move A.08.09.004; Oats drink, A.08.09.005; Rice drink and A.08.09.008; Soya drink to 1.8 Dairy analogues.
- Alcoholic beverages. Separate beer, wines, spirits, etc. (see above).
- Desserts. Unclear where dairy-based desserts (not yogurt) belong. Unclear where instant dessert mixes belong

<u>Conclusions</u>

The FAIM categorisation system is a compromise between simplicity and accuracy. Industry experts feel that there are some important sub-categories where additive use levels may be significantly different that have been overlooked. This applies particularly to processed fruit and vegetables, confectionery, processed meat, non-alcoholic drinks and alcoholic drinks. The absence of these sub-categories will result in inappropriate use levels being applied across the broader categories resulting in unnecessary over-estimation of intakes.

Some FAIM categories contain FoodEx categories that are not relevant to additive exposure. This applies particularly to unprocessed meat, where the number of approved applications is limited apart from the use of colours for health marking. In other cases FAIM and FoodEx categories are mis-matched such as for sauces.

Section 2 – Food classification recommendations

Aim:

Consider additional usage categories in the EFSA FOODEX system that could be relevant to the specific uses of food additives identified in FDE usage surveys by providing an additional break-out of Regulation (EU) No 1129/2011 categories. Recommend suitable food categorisation system for food additives exposure modelling system.

Recommendation

A food categorisation system based on the Regulation (EU) No 1129/2011 categories and modified taking into consideration recommendation made in Section 1 of this report and available categories in FoodEx, is attached (Table 2.1). This table has been developed in consultation with experts from the food additive producer and additive user industries and reflects a detailed knowledge of the patterns of use and variations in use levels that are likely to occur across a broad range of additive categories. This system is intended to represent a development of the FAIM system for use in a simple exposure screening model. A considerably more detailed categorisation system would be required for a distributional/probabilistic model based on diary data, such as is used in the FACET system.

Because of the limited time available for this consultation, the table should be regarded as a initial proposal and will benefit from further discussion and development with industry experts.

Table 2.1. Proposed classification system for simple food additives dietary exposure model

Group	Category	
1	Dairy products and analogues (1)	
	1.1	Unflavoured pasteurised and sterilised (including UHT) milk (1.1)
	1.2	Unflavoured fermented milk products
	1.4	Flavoured fermented milk products including heat treated products (1.4)
	1.5	Dehydrated milk as defined by Directive 2001/114/EC (1.5)
	1.6	Cream and cream powder (1.6)
	01.6.1	Unflavoured cream
	01.6.3	Other creams (1.6.3)
	01.7.1	Unripened cheese excluding products falling in category 16 (1.7.1)
	01.7.2	Ripened cheese (1.7.2)
	01.7.3	Edible cheese rind (1.7.3)
	01.7.4	Whey cheese (1.7.4)
	01.7.5	Processed cheese (1.7.5)
	01.7.6	Cheese products (excluding products falling in category 16) (1.7.6)
	1.8	Dairy analogues, including beverage whiteners (1.8)
2	Fats and oils and fat and oil emulsions (2)	
	2.1	Fats and oils essentially free from water (excluding anhydrous milkfat) (2.1)
	2.2	Fat and oil emulsions mainly of type water-in-oil (2.2)
	2.3	Vegetable oil pan spray (2.3)
3	Ices	
	3.1	Edible ices with sugar
	3.2	Edible ices with no added sugar
4	Fruit and vegetables (4)	
	4.1	Unprocessed fruit and vegetables (4.1)
	4.2	Processed fruit and vegetables (4.2)
	04.2.1	Dried fruit and vegetables (4.2.1)
	04.2.2	Fruit and vegetables in vinegar, oil, or brine (4.2.2)
	04.2.3	Canned or bottled fruit and vegetables (4.2.3)
	04.2.4	Fruit and vegetable preparations, excluding products covered by 5.4 (4.2.4)
	04.2.4.1	Fruit and vegetable preparations excluding compote (4.2.4.1)
	04.2.4.2	Compote, excluding products covered by category 16 (4.2.4.2)
	04.2.5	Jam, jellies and marmalades and similar products (4.2.5)

Group	Category	
	04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC (4.2.5.1)
	04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC (4.2.5.2)
	04.2.5.3	Other similar fruit or vegetable spreads (4.2.5.3)
	04.2.5.4	Nut butters and nut spreads (4.2.5.4)
	04.2.6	Processed potato products (4.2.6)
5	Confectionery (5)	
	5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC (5.1)
	5.2.1	Other confectionery including breath refreshening microsweets with sugar
	5.2.2	Other confectionery including breath refreshening microsweets with no added sugar
	5.3	Chewing gum (5.3)
	5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 (5.4)
6	Cereals and cereal products (6)	
	6.1	Whole, broken, or flaked grain (6.1)
	6.2	Flours and starches (6.2)
	6.3	Breakfast cereals (6.3)
	6.4	Pasta (6.4)
	6.5	Noodles (6.5)
	6.6	Batters (6.6)
	6.7	Pre-cooked or processed cereals (6.7)
7	Bakery wares (7)	
	7.1	Bread and rolls (7.1)
	7.2	Fine bakery wares (7.2)
	7.2.1	Cereal bars
	7.2.2	Pastries and cakes
	7.2.3	Biscuits (cookies)
8	Meat (8)	
	8.1	Unprocessed meat: breakfast sausages, burger meat, gehakt and pre-packed preparations of fresh minced meat
	8.2	Processed meat (8.2)
	08.2.1	Non heat treated processed meat (8.2.1)
	08.2.2	Heat treated processed meat (8.2.2)
	08.2.3	Casings and coatings and decorations for meat (8.2.3)
	08.2.4	Traditionally cured meat products with specific provisions concerning nitrites and nitrates (8.2.4)
9	Fish and fisheries products (9)	
	9.1	Unprocessed fish and fisheries products (9.1)

Group	Category	
	09.1.1	Unprocessed fish (9.1.1)
	09.1.2	Unprocessed molluscs and crustaceans (9.1.2)
	9.2	Processed fish and fishery products including molluscs and crustaceans (9.2)
	9.3	Fish roe (9.3)
10	Eggs and egg products (10)	
	10.1	Unprocessed eggs (10.1)
	10.2	Processed eggs and egg products (10.2)
11	Sugars, syrups, honey and table-top sweeteners (11)	
	11.1	Sugars and syrups as defined by Directive 2001/111/EC (11.1)
	11.2	Other sugars and syrups (11.2)
	11.3	Honey as defined in Directive 2001/110/EC (11.3)
	11.4	Table Top Sweeteners (11.4)
12	Salts, spices, soups, sauces, salads and protein products (12)	
	12.1	Salt and salt substitutes (12.1)
	12.2	Herbs, spices, seasonings, condiments (12.2)
	12.3	Vinegars (12.3)
	12.4	Mustard (12.4)
	12.5	Soups and broths (12.5)
	12.6	Savoury sauces
	12.6.1	Savoury sauces other than ketchups and condiments
	12.6.2	Ketchups, condiments
	12.6.3	Dried / concentrated suaces
	12.7	Salads and savoury based sandwich spreads (12.7)
	12.8	Yeast and yeast products (12.8)
	12.9	Protein products, excluding products covered in category 1.8 (12.9)
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC (13)	
	13.1	Foods for infants and young children (13.1)
	13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)
	13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal
	13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009 (13.4)
14	Beverages (14)	
	14.1	Non-alcoholic beverages (14.1)
	14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
	14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices (14.1.2)

Group	Category	
	14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products (14.1.3)
	14.1.4.1	Flavoured drinks with sugar
	14.1.4.1.1	Containing fruit,
	14.1.4.1.2	Flavoured,
	14.1.4.1.3	Colas,
	14.1.4.1.4	Dairy-based drinks
	14.1.4.2	Flavoured drinks with no added sugar
	14.1.4.2.1	Containing fruit,
	14.1.4.2.2	Flavoured,
	14.1.4.2.3	Colas,
	14.1.4.2.4	Dairy-based drinks
	14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations
	14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts (14.2)
	14.2.1	Beer and malt beverages (14.2.1)
	14.2.2	Wine and other products defined by Regulation (EEC) No 1234/2007, and alcohol free counterparts (14.2.2)
	14.2.3	Cider and perry (14.2.3)
	14.2.4	Fruit wine and made wine (14.2.4)
	14.2.5	Mead (14.2.5)
	14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008 (14.2.6)
	14.2.7	Aromatised wine-based products as defined by Regulation (EEC) No 1601/91 (14.2.7)
	14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol and (14.2.8)
15	Ready-to-eat savouries and snacks (15)	
	15.1	Potato-, cereal-, flour- or starch-based snacks (15.1)
	15.2	Processed nuts (15.2)
16	Desserts excluding products covered in category 1, 3 and 4 (16)	
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children (17)	
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children (18)	

Section 3 – Food consumption data

Aim:

Evaluate the food consumption data provided in the FAIM by estimating energy intakes associated with each food type using international food composition data and comparing average and 95th percentiles from each food category and total energy intake from all foods combined with WHO nutrient requirements guidelines for each age group.

Background

The FAIM additive intake model uses data taken from the EFSA Comprehensive European Food Consumption database. This database is a compilation of data collected by 15 member states and covering age ranges from one year upwards. The Guidelines for use of the Comprehensive database[4] advise against using the data for international comparisons because the methods used to collect the data differed considerably from one country to another. One major difference is the duration of the surveys that can range from one day (24 hour recall) up to 7 days. When EFSA published the summary data from the Comprehensive data base up to Level L2 in the coding system, they noted that surveys of less than two days would be unsuitable for chronic exposure assessments and so they divide the data into those suitable for acute or chronic. It is not stated but assumed that the FAIM data are based on 2-day or more surveys.

Two day surveys are likely to produce over-estimates of foods that are less frequently consumed. Furthermore, some of the two-day surveys were not conducted on consecutive days and so this is similar to using one-day data. These may also instances where individuals did not complete more than one day of the survey and these data have not been removed.

As a consequence it is likely that for certain foods that are less frequently consumed the Comprehensive database will contain unrealistically high values for upper level consumption. This can be tested to some extent by considering the energy intake resulting from the consumption of these foods. As a first step the total energy intake has been estimated using the FAIM method.

Approach

Energy intakes

Energy content of foods was taken from the UK Nutrient Databank (McCance and Widdowson,[5]). Food descriptions were matched with each of the FAIM food categories and

[4] European Food Safety Authority; Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097.

[5] http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/science/dietarysurveys/dietsurveys/

the average energy content calculated (Table 3.1). The energy intake was calculated using the FAIM system for average and for high level consumers. Total energy intake for each age groups was then compared with international recommendations for average energy requirements for each group (FAO/WHO[6], ref). Numbers of consumers

The Guidelines published to accompany the EFSA Comprehensive database state that estimates of upper percentiles are statistically unreliable if the number of individuals consuming a particular food falls below a statistically significant number. At the 95th percentile, values based on less than 60 reporting individuals are considered to be unreliable and have therefore not been used in these assessments.

In the FAIM model, when the number of consumers per age class for a food category was below 60, the high level was estimated as the mean consumption of consumers-only. The model also indicated with a red background values based on 5 individuals or less. This aspect has been covered adequately by the model and requires no further consideration.

Results

Total energy intake

The Results of FAIM energy modelling are provided in Table 3.2. 'Mean' values represent that average energy intake for all individuals in each population sub-group. For adults, adolescents and the elderly there is reasonable agreement with energy requirements although some evidence of under-estimation for the older age-groups. The reverse is true for children and toddlers, where the model appears to over-estimate energy intakes (and thus food consumption) by a significant margin. When high-level consumers of individual foods are considered, you would still expect their energy intake to conform to long-term requirements. However, significantly more over-estimation is evident, especially for children and toddlers. In some cases energy intake is 2-3 times the requirement.

[6] FAO Food and Nutrition Series 1. Human energy requirements. Report of a Joint FAO/WHO/UNU Expert Consultation. Rome, 17–24 October 2001.

Table 3.1 Calorie content of FAIM category foods

FCS name Level 2	Row Labels	Average of Energy (kJ/100g)	kj/kg
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	1.1	255	2545
1.23 - Unflavoured fermented milk products, including natural unflavoure	1.23	436	4364
1.4 - Flavoured fermented milk products including heat treated products	1.4	702	7024
1.5 - Dehydrated milk as defined by Directive 2001/114/EC		0	
1.6 - Cream	1.6	1067	10669
1.7.1 - Unripened cheese (excl cat 16)	1.7.1	1350	13495
1.7.2 - Ripened cheese	1.7.2	1443	14433
1.7.4 - Whey cheese			
1.7.5 - Processed cheese	1.7.5	963	9633
1.8 - Dairy analogues, including beverage whiteners	1.8	1214	12143
2.1 - Fats and oils essentially free from water (excluding anhydrous milkfa	2.1	3567	35667
2.2 - Fat and oil emulsions mainly of type water-in-oil	2.2	1747	17468
3 - Edible ices	3	820	8199
4.1 - Unprocessed fruit and vegetables	4.1	405	4053
4.2 - Processed fruit and vegetables	4.2	671	6707
5.1 - Cocoa and Chocolate products as covered by Directive 2000/36/EC	5.1	2036	20362
5.2.1 - Other confectionery with added sugar	5.2.1	1558	15579
5.2.2 - Other confectionery without added sugar			
5.3.1 - Chewing gum with added sugar			
5.3.2 - Chewing gum without added sugar			
6.1 - Whole, broken, or flaked grain	6.1	866	8658
6.2 - Flours and starches	6.2	1430	14300
6.3 - Breakfast cereals	6.3	1416	14162
6.4 - Pasta	6.4	1008	10078
6.5 - Noodles	6.5	905	9047
7.1 - Bread and rolls	7.1	1143	11429
7.2 - Fine bakery wares	7.2	1467	14675
8.1 - Unprocessed meat	8.1	888	8880
8.2 - Processed meat	8.2	895	8954
9.1.1 - Unprocessed fish	9.1.1	595	5948
9.1.2 - Unprocessed crustaceans and molluscs	9.1.2	426	4265
9.2 - Processed fish and fishery products including mollusks and crustacear	9.2	766	7657
9.3 - Fish roe	9.3	712	7124
10.1 - Unprocessed eggs	10.1	795	7951
10.2 - Processed eggs and egg products	10.2	1190	11900
11.1 - Sugars and syrups as defined by Directive 2001/111/EC	11.1	1646	16463
11.2 - Other sugars and syrups	11.2	1170	11700
11.3 - Honey as defined in Directive 2001/110/EC	11.3	1215	12150
11.4 - Table Top Sweeteners			
12.1 - Salt and salt substitutes	12.1		
12.2 - Herbs, spices, seasonings	12.2	821	8213
12.3 - Vinegars			
12.4 - Mustard	12.4	702	7017
12.5 - Soups and broths	12.5	232	2322
12.6 - Sauces	12.6	771	7713
12.7 - Salads and savoury based sandwich spreads	12.7	1074	10737
12.8 - Yeast and yeast products	12.8	569	5687
12.9 - Protein products, excluding products covered in category 1.8			
13.1 - Foods for infants and young children	13.1	623	6235
13.2 - Dietary foods for special medical purposes defined in Directive 1999	13.2	510	5100
13.3 - Dietary foods for weight control diets intended to replace total daily	13.3	820	8195
13.4 - Foods suitable for people intolerant to gluten as defined by Regulat	13.4		
14.1.1 - Water, including natural mineral water as defined in Directive 200	14.1.1		
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	14.1.2.1	374	3739
14.1.2.2 - Vegetable juices	14.1.2.2	62	620
14.1.3 - Fruit nectars as defined by Council Directive 2001/112/EC and vege	14.1.3	482	4815
14.1.4 Flavoured drinks / 14.1.4.1 - Flavoured drinks with sugar (1)	14.1.4.1	268	2676
14.1.4 Flavoured drinks / 14.1.4.2 - Flavoured drinks with sweeteners (1)	14.1.4.2	28	275
14.1.5 - Coffee, tea, , herbal and fruit infusions, chicory, tea; tea, herbal an	14.1.5	87	873
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counter	14.2	406	4065
15.1 - Potato-, cereal-, flour- or starch-based snacks	15.1	1970	19699
15.2 - Processed nuts	15.2	1821	18207
16 - Desserts excluding products covered in category 1, 3 and 4	16	804	8036
17 - Food supplements as defined in Directive 2002/46/EC[5] excluding foc	17		
18 - Processed foods not covered by categories 1 to 17	18	948	9477
99 - Unclassified foods			

Break-down of foods that are contributing to high energy intakes.

After establishing total energy associated with each population group the data were reassessed to consider energy intakes from individual foods for high level (95th percentile) consumers. Foods that resulted in energy intake of more than 20% of the average energy requirement for each age group when consumed at the 95th percentiles were identified (Tables 3.3 to 3.7). It is to be expected that there will be variations in patterns of food consumption so that some consumers will obtain a higher proportion of their energy intake from any given food category than others. This is certainly likely to be the case for dietary staples such as milk, cereal-based foods (bread, pasta, rice) and starchy vegetables such as potatoes. The question is whether high energy intakes from other foods are due to variations in individual food choices over the longer term or because the survey duration was too short to capture true long-term consumption.

Foods where the energy contribution for high level consumers appear unexpectedly high have been highlighted in Tables 3.3 to 3.7. Expert nutritional advice would need to be sought to confirm whether or not these would represent true long-term consumption patterns. However, is seem unlikely that a toddler or child would obtain up to 20% of energy requirements from fats and oils, 69% from flavoured fermented milk products, 21% from snack foods, 35% from breakfast cereals or 26% from desserts in the long term. The energy contribution from processed fruit and vegetables of up to 37% may reflect a coding error if normally cooked foods are counted in this category. Similarly the apparent energy contribution of up to 45% from fine bakery wares could reflect the inclusion of some general baked goods in this category. Children seem to have more occurrences of foods contributing more than 20% to total energy than toddlers but the pattern is similar. An exception is '1.8 - Dairy analogues, including beverage whiteners' in the Netherlands, where children can obtain over 200 kJ/kg/bw/day or 74% of their requirements.

For adolescents the apparent energy intake of up to 45% from alcoholic beverages requires investigation. According to the Comprehensive database, adolescents in Belgium and Germany consume about two litres of 'Beer and beer-like beverages' daily at the 95th percentile (20 - 30 g/kg bw/day). Adults in the Czech Republic and Ireland appear to consume more, contributing over 50% of daily energy requirements. Some adults also appear to obtain 24% of their energy requirements from snack foods.

Conclusion

This assessment provides a quantitative indication of the degree of conservatism inherent in the FAIM system. There appears to be an overall over-estimation of food consumption that particularly affects younger children. This is dependent on assumptions made about the energy content of the foods and with more time a clearer analysis could be produced.

Certain foods within particular population groups appear to be contributing higher energy intakes than would be consistent with long-term consumption particularly for children. These include fats and oils, flavoured fermented dairy products, snack foods, processed fruit and vegetables, desserts and fine bakery wares. For adolescents the apparent consumption of two litres of alcoholic drinks ('beer and beer-like drinks') requires investigation.

The food consumption data in the FAIM system should be subject to a quality review to identify values that are not representative of true long-term consumption. The presence of

such values in a system that is so dependent on the use of one 95th percentile consumption value to determine the major part of the exposure can introduce significant distortions. These values should then be either adjusted using energy requirement data or removed from the system.

Table 3.2. Results of energy intake modelling using FAIM system

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Energy

SUMMARY per AGE CLASS and SURVEY (kj/kg bw/day)

	MPL		Use levels		Energy needs	High level
	Mean	High level	Mean	High level	(kj/kg bw/day)	% average
Toddlers						
Bulgaria (Nutrichild)	0.0	0.0	509.7	726.0	335 - 350	212%
Finland (DIPP)	0.0	0.0	547.1	874.9	335 - 350	255%
Germany (Donald 2006_2008)	0.0	0.0	403.7	663.3	335 - 350	194%
The Netherlands (VCP_Kids)	0.0	0.0	487.2	671.2	335 - 350	196%
Children						
Belgium (Regional_Flanders)	0.0	0.0	448.6	610.8	267 - 334	204%
Bulgaria (Nutrichild)	0.0	0.0	457.2	533.5	267 - 334	178%
Czech Republic (SISP04)	0.0	0.0	359.7	406.1	267 - 334	135%
Denmark (Danish Dietary Survey)	0.0	0.0	357.8	402.6	267 - 334	134%
Finland (DIPP)	0.0	0.0	403.6	466.6	267 - 334	156%
Finland (STRIP)	0.0	0.0	367.6	443.4	267 - 334	148%
France (INCA 2)	0.0	0.0	358.6	411.5	267 - 334	137%
Germany (Donald 2006_2008)	0.0	0.0	322.9	446.5	267 - 334	149%
Greece (Regional_Crete)	0.0	0.0	308.0	367.3	267 - 334	122%
Italy (INRAN_SCAI_2005_06)	0.0	0.0	362.6	406.9	267 - 334	136%
Latvia (EFSA_TEST)	0.0	0.0	260.0	320.6	267 - 334	107%
The Netherlands (VCP_Kids)	0.0	0.0	410.6	626.7	267 - 334	209%
Spain (enKid)	0.0	0.0	359.8	436.5	267 - 334	145%
Spain (Nut_Ink05)	0.0	0.0	337.2	372.1	267 - 334	124%
Sweden (NFA)	0.0	0.0	357.9	420.4	267 - 334	140%
Adolescents						
Belgium (Diet_National_2004)	0.0	0.0	173.7	274.6	185 - 279	117%
Cyprus (Childhealth)	0.0	0.0	157.0	189.2	185 - 279	81%
Czech Republic (SISP04)	0.0	0.0	251.3	299.5	185 - 279	128%
Denmark (Danish Dietary Survey)	0.0	0.0	206.7	237.5	185 - 279	102%
France (INCA 2)	0.0	0.0	185.0	223.6	185 - 279	96%
Germany (National_Nutrition_Survey_II)	0.0	0.0	150.8	229.0	185 - 279	98%
Italy (INRAN_SCAI_2005_06)	0.0	0.0	211.6	244.4	185 - 279	104%
Latvia (EFSA_TEST)	0.0	0.0	190.8	239.1	185 - 279	102%
Spain (AESAN_FIAB)	0.0	0.0	172.1	195.4	185 - 279	83%
Spain (enKid)	0.0	0.0	216.7	258.2	185 - 279	110%
Spain (Nut_Ink05)	0.0	0.0	202.7	233.0	185 - 279	100%
Sweden (NFA)	0.0	0.0	219.7	295.4	185 - 279	126%
Adults						
Belgium (Diet_National_2004)	0.0	0.0	155.2	208.1	183	114%
Czech Republic (SISP04)	0.0	0.0	162.5	259.8	183	142%
Denmark (Danish_Dietary_Survey)	0.0	0.0	159.9	198.5	183	108%
Finland (FINDIET_2007)	0.0	0.0	142.2	216.0	183	118%
France (INCA2)	0.0	0.0	146.6	190.2	183	104%
Germany (National_Nutrition_Survey_II)	0.0	0.0	145.7	199.7	183	109%
Hungary (National_Repr_Surv)	0.0	0.0	153.2	177.3	183	97%
Ireland (NSIFCS)	0.0	0.0	170.0	246.2	183	135%
Italy (INRAN_SCAI_2005_06)	0.0	0.0	153.1	175.7	183	96%
Latvia (EFSA_TEST)	0.0	0.0	135.8	167.4	183	91%
The Netherlands (DNFCS_2003)	0.0	0.0	166.5	283.1	183	155%
Spain (AESAN)	0.0	0.0	147.1	174.5	183	95%
Spain (AESAN_FIAB)	0.0	0.0	159.1	186.1	183	102%
Sweden (Riksmaten_1997_98)	0.0	0.0	168.3	206.7	183	113%
United Kingdom (NDNS)	0.0	0.0	138.4	196.7	183	107%
The elderly						
Belgium (Diet_National_2004)	0.0	0.0	141.2	190.8	183	104%
Denmark (Danish_Dietary_Survey)	0.0	0.0	158.5	189.3	183	103%
Finland (FINDIET_2007)	0.0	0.0	121.6	160.0	183	87%
France (INCA2)	0.0	0.0	143.9	168.9	183	92%
Germany (National_Nutrition_Survey_II)	0.0	0.0	139.5	188.1	183	103%
Hungary (National_Repr_Surv)	0.0	0.0	138.6	156.8	183	86%
Italy (INRAN_SCAI_2005_06)	0.0	0.0	144.3	169.3	183	93%

Table 3.3 Energy intakes from individual food consumed at the 95th percentile - Toddlers

Bulgaria	**Energy, kJ, 95th %-ile**	**% energy requirement**
1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)	168	49%
2.1 - Fats and oils essentially free from water (excluding anhydrous milkfat)	**71**	**21%**
4.1 - Unprocessed fruit and vegetables	147	43%
7.1 - Bread and rolls	126	37%
7.2 - Fine bakery wares	**129**	**38%**
8.1 - Unprocessed meat	98	29%
13.1 - Foods for infants and young children	229	67%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	103	30%
14.1.3 - Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	102	30%
15.1 - Potato-, cereal-, flour- or starch-based snacks	**73**	**21%**
Finland DIPP		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	218	64%
1.4 - Flavoured fermented milk products including heat treated products	147	43%
4.1 - Unprocessed fruit and vegetables	113	33%
4.2 - Processed fruit and vegetables	**126**	**37%**
6.2 - Flours and starches	115	34%
13.1 - Foods for infants and young children	453	132%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	80	23%
Germany		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	119	35%
1.4 - Flavoured fermented milk products including heat treated products	99	29%
4.1 - Unprocessed fruit and vegetables	116	34%
7.1 - Bread and rolls	100	29%
13.1 - Foods for infants and young children	337	98%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	83	24%
Netherlands		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	103	30%
1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)	113	33%
1.4 - Flavoured fermented milk products including heat treated products	**237**	**69%**
1.7.1 - Unripened cheese (excl cat 16)	74	22%
1.8 - Dairy analogues, including beverage whiteners	76	22%
4.1 - Unprocessed fruit and vegetables	82	24%
7.1 - Bread and rolls	113	33%
7.2 - Fine bakery wares	94	28%
13.1 - Foods for infants and young children	113	33%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	162	47%
14.1.4.1 - Flavoured drinks with sugar	**80**	**23%**
16 - Desserts excluding products covered in category 1, 3 and 4	111	32%

Table 3.4 Energy intakes from individual food consumed at the 95th percentile - Children

	Energy, kJ, 95th %-ile	% energy requirement
Belgium		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	91	30%
1.4 - Flavoured fermented milk products including heat treated products	**203**	**68%**
1.7.1 - Unripened cheese (excl cat 16)	100	33%
4.1 - Unprocessed fruit and vegetables	82	27%
4.2 - Processed fruit and vegetables	**72**	**24%**
7.1 - Bread and rolls	99	33%
7.2 - Fine bakery wares	78	26%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	125	42%
14.1.4.1 - Flavoured drinks with sugar	**97**	**32%**
16 - Desserts excluding products covered in category 1, 3 and 4	**78**	**26%**
Bulgaria		
1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)	94	31%
2.1 - Fats and oils essentially free from water (excluding anhydrous milkfat)	**78**	**26%**
4.1 - Unprocessed fruit and vegetables	134	45%
7.1 - Bread and rolls	139	46%
7.2 - Fine bakery wares	**136**	**45%**
8.1 - Unprocessed meat	90	30%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	93	31%
14.1.3 - Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	80	27%
14.1.4.1 - Flavoured drinks with sugar	62	21%
Czech Republic		
1.4 - Flavoured fermented milk products including heat treated products	62	21%
4.1 - Unprocessed fruit and vegetables	95	32%
6.3 - Breakfast cereals	**92**	**31%**
7.1 - Bread and rolls	79	26%
7.2 - Fine bakery wares	92	31%
8.1 - Unprocessed meat	63	21%
14.1.4.1 - Flavoured drinks with sugar	**82**	**27%**
Denmark		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	85	28%
4.1 - Unprocessed fruit and vegetables	89	30%
7.1 - Bread and rolls	108	36%
Finland DIPP		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	129	43%
1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)	67	22%
1.4 - Flavoured fermented milk products including heat treated products	**85**	**28%**
4.1 - Unprocessed fruit and vegetables	70	23%

Table 3.4 Cont'd

	Energy, kJ, 95th %-ile	% energy requirement
4.2 - Processed fruit and vegetables	**76**	**25%**
6.2 - Flours and starches	79	26%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	99	33%
Finland STRIP		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	74	25%
4.2 - Processed fruit and vegetables	62	21%
6.3 - Breakfast cereals	**106**	**35%**
7.2 - Fine bakery wares	**85**	**28%**
France		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	64	21%
1.7.1 - Unripened cheese (excl cat 16)	68	23%
4.1 - Unprocessed fruit and vegetables	62	21%
4.2 - Processed fruit and vegetables	61	20%
7.2 - Fine bakery wares	**99**	**33%**
11.2 - Other sugars and syrups	**64**	**21%**
13.1 - Foods for infants and young children	62	21%
Germany		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	60	20%
1.4 - Flavoured fermented milk products including heat treated products	62	21%
4.1 - Unprocessed fruit and vegetables	75	25%
7.1 - Bread and rolls	79	26%
13.1 - Foods for infants and young children	127	42%
14.1.4.1 - Flavoured drinks with sugar	**65**	**22%**
Greece		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	85	28%
4.2 - Processed fruit and vegetables	**77**	**26%**
6.1 - Whole, broken, or flaked grain	65	22%
6.4 - Pasta	88	29%
7.1 - Bread and rolls	64	21%
7.2 - Fine bakery wares	**96**	**32%**
12.7 - Salads and savoury based sandwich spreads	61	20%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	66	22%
Italy		
2.1 - Fats and oils essentially free from water (excluding anhydrous milkfat)	79	26%
4.1 - Unprocessed fruit and vegetables	90	30%
7.1 - Bread and rolls	88	29%
7.2 - Fine bakery wares	**74**	**25%**

Table 3.4 Cont'd

	Energy, kJ, 95th %-ile	% energy requirement
Latvia		
4.2 - Processed fruit and vegetables	74	25%
6.3 - Breakfast cereals	66	22%
7.1 - Bread and rolls	70	23%
7.2 - Fine bakery wares	88	29%
Netherlands		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	77	26%
1.23 - Unflavoured fermented milk products, i	79	26%
1.4 - Flavoured fermented milk products including heat treated products	**200**	**67%**
1.7.1 - Unripened cheese (excl cat 16)	75	25%
1.8 - Dairy analogues, including beverage whiteners	**223**	**74%**
4.1 - Unprocessed fruit and vegetables	69	23%
7.1 - Bread and rolls	93	31%
7.2 - Fine bakery wares	**97**	**32%**
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	122	41%
14.1.4.1 - Flavoured drinks with sugar	62	21%
16 - Desserts excluding products covered in category 1, 3 and 4	79	26%
Spain enkid		
1.4 - Flavoured fermented milk products including heat treated products	**98**	**33%**
1.7.5 - Processed cheese	**81**	**27%**
4.1 - Unprocessed fruit and vegetables	78	26%
4.2 - Processed fruit and vegetables	62	21%
7.1 - Bread and rolls	84	28%
7.2 - Fine bakery wares	**86**	**29%**
8.1 - Unprocessed meat	75	25%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	77	26%
Spain nut		
1.4 - Flavoured fermented milk products including heat treated products	68	23%
1.7.1 - Unripened cheese (excl cat 16)	67	22%
6.4 - Pasta	64	21%
7.1 - Bread and rolls	76	25%
7.2 - Fine bakery wares	67	22%
8.1 - Unprocessed meat	63	21%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	67	22%
Sweden		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	72	24%
1.4 - Flavoured fermented milk products including heat treated products	87	29%
4.2 - Processed fruit and vegetables	83	28%
6.3 - Breakfast cereals	63	21%
7.2 - Fine bakery wares	83	28%
13.1 - Foods for infants and young children	75	25%
13.2 - Dietary foods for special medical purposes	73	24%
14.1.4.1 - Flavoured drinks with sugar	67	22%

Table 3.5 Energy intakes from individual food consumed at the 95th percentile - Adolescents

	Energy, kJ, 95th %-ile	% energy requirement
Belgium		
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**105**	**45%**
14.1.4.1 - Flavoured drinks with sugar	60	26%
7.2 - Fine bakery wares	46	20%
Czech Republic		
14.1.4.1 - Flavoured drinks with sugar	58	25%
7.1 - Bread and rolls	70	30%
7.2 - Fine bakery wares	**73**	**31%**
4.1 - Unprocessed fruit and vegetables	65	28%
Denmark		
7.1 - Bread and rolls	65	28%
France		0%
11.2 - Other sugars and syrups	50	21%
7.2 - Fine bakery wares	63	27%
Germany		
7.1 - Bread and rolls	53	23%
7.2 - Fine bakery wares	66	28%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	80	34%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**82**	**35%**
Italy		
4.1 - Unprocessed fruit and vegetables	54	23%
7.1 - Bread and rolls	58	25%
4.2 - Processed fruit and vegetables	54	23%
7.1 - Bread and rolls	66	28%
7.2 - Fine bakery wares	**66**	**28%**
Spain enKID		
1.7.5 - Processed cheese	53	23%
7.1 - Bread and rolls	73	31%
7.2 - Fine bakery wares	57	25%
8.1 - Unprocessed meat	47	20%
Spain nut		**0%**
7.1 - Bread and rolls	60	26%
Sweden		
1.1 - Unflavoured pasteurised and sterilised (including UHT) milk	51	22%
1.4 - Flavoured fermented milk products including heat treated products	55	23%
4.2 - Processed fruit and vegetables	53	23%
7.2 - Fine bakery wares	55	23%
13.1 - Foods for infants and young children	76	32%

Table 3.6 Energy intakes from individual food consumed at the 95th percentile - Adults

	Energy, kJ, 95th %-ile	% energy requirement
Belgium		
7.1 - Bread and rolls	46	25%
7.2 - Fine bakery wares	42	23%
14.1.4.1 - Flavoured drinks with sugar	**51**	**28%**
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**64**	**35%**
Czech Republic		
7.1 - Bread and rolls	51	28%
7.2 - Fine bakery wares	48	26%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**120**	**65%**
Denmark		
4.1 - Unprocessed fruit and vegetables	41	22%
7.1 - Bread and rolls	46	25%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	55	30%
Finland		
6.2 - Flours and starches	41	23%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	81	44%
15.1 - Potato-, cereal-, flour- or starch-based snacks	**43**	**24%**
France		
7.1 - Bread and rolls	41	23%
11.2 - Other sugars and syrups	45	25%
Germany		
1.8 - Dairy analogues, including beverage whiteners	56	30%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	65	35%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**66**	**36%**
Hungary		
4.1 - Unprocessed fruit and vegetables	44	24%
7.1 - Bread and rolls	49	27%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	43	23%
Ireland		
4.2 - Processed fruit and vegetables	**55**	**30%**
7.1 - Bread and rolls	41	22%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**96**	**53%**

Table 3.6 Cont'd

	Energy, kJ, 95th %-ile	% energy requirement
Italy		
4.1 - Unprocessed fruit and vegetables	48	26%
7.1 - Bread and rolls	42	23%
Latvia		
7.1 - Bread and rolls	53	29%
7.2 - Fine bakery wares	44	24%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	42	23%
Netherlands		
1.4 - Flavoured fermented milk products including heat treated products	51	28%
7.1 - Bread and rolls	46	25%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**129**	**70%**
Spain AESAN		
4.1 - Unprocessed fruit and vegetables	52	28%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	47	26%
Spain FIAB		
4.1 - Unprocessed fruit and vegetables	56	31%
Sweden		
6.3 - Breakfast cereals	**47**	**26%**
UK		
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**74**	**41%**

Table 3.7 Energy intakes from individual food consumed at the 95th percentile - Elderly

	Energy, kJ, 95th %-ile	% energy requirement
Belgium		
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	47	26%
6.3 - Breakfast cereals	**52**	**28%**
Denmark		
4.1 - Unprocessed fruit and vegetables	43	23%
7.1 - Bread and rolls	42	23%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	49	27%
Finland		
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	41	22%
France		
4.1 - Unprocessed fruit and vegetables	45	25%
7.1 - Bread and rolls	46	25%
Germany		
7.1 - Bread and rolls	42	23%
7.2 - Fine bakery wares	48	26%
14.1.2.1 - Fruit juices as defined by Council Directive 2001/112/EC	49	27%
14.2 - Alcoholic beverages, including alcohol-free and low-alcohol counterparts	**60**	**33%**
Hungary		
4.1 - Unprocessed fruit and vegetables	42	23%
Italy		
4.1 - Unprocessed fruit and vegetables	54	29%
7.1 - Bread and rolls	47	26%

Section 4 – Methodological evaluation

Aim:

To evaluate the total exposure calculation method used in FAIM and compare results with alternative approaches that take 'typical' usage into consideration alongside maximum levels. In particular a spread sheet model initially developed for screening exposures to food colours and the FACET system.

Introduction

Dietary exposure to food additives may be undertaken for a variety of purposes. When a new additive is being developed and an application for authorisation is being prepared the applicant will want to test the technologically desirable use levels against the potential ADI to ensure that consumer safety is not compromised. If there is any risk of the ADI being exceeded then the manufacturer may investigate different patterns of usage to ensure that the ADI is not exceeded. EFSA and the ANS Panel will want to use a similar approach when they are asked to evaluate the application dossier by the European Commission. For such a new additive there is no history of use and applicants will need to base estimates of normal and maximum use levels as required by Regulation 234/2011[7] on technological need.

For additives that have a long history of use the situation is very different. Additive users will have developed patterns of use that apply the minimum necessary to achieve the desired technological effect and this level can vary widely within a category of food because of different physical and chemical characteristics of the food such as fat content, pH, water content, presence of other competing or complimentary additives, turbidity, density, etc. This is best illustrated with the example of food colours where a wide range of usage is required corresponding to different flavours of varieties of food products.

This means that when evaluating the safety of food additives with an established pattern of use, this additional information must be taken into consideration if reliable estimates of exposure are to be produced. This means that methods suitable for assessing the theoretical exposure to new additives will not necessarily be suitable for assessing actual exposures to established additives.

In the EFSA call for data to support the re-evaluation of food colours, colour manufacturers and users were invited to provide:

> "Information on the present use and use patterns of the food colours, including lakes (which food categories and subcategories, proportion of foods within categories/subcategories in which it is used, normal use levels as well as any

[7] Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.. OJ L 64/15; 11.3.2011

maximum use levels, especially for those uses which are only limited by *quantum satis* (q.s.))."

Which is consistent with the requirements of Regulation 234/2011. Food additive producers and users have gone to considerable lengths to obtain the data requested by EFSA to support this re-evaluation. In most cases they have been able to provide a range of typical use levels that reflect the normal pattern of usage as well as maximum use levels that reflect some exceptional applications. For food colours this is illustrated with the example of a colour such as a yellow. Most normal or typical applications relate to vanilla or lemon flavours but in exceptional cases a deeper colour may be required such as for a mango sorbet of for certain seasonal Easter cakes.

A typical consumer will be exposed to range of use levels within a given food commodity over an extended period of time so that 'typical' use levels will be more representative of chronic exposure scenarios. The exception to this would occur when strong brand or variety loyalty leads an individual to always consume a product that contains a particular level of a food colour. It is possible that such a product contains the colour at the maximum level and so this scenario should be included in the exposure analysis.

It is very unlikely, however, that a consumer would exhibit such 'consumer loyalty' to more than one product simultaneously or that all products would contain the additive at the maximum level. Such scenarios should therefore be excluded from the assessment because they do not reflect a situation that could reasonably be expected to occur in reality.

A realistic screening method for food additive exposures should therefore take account of normal and maximum use levels and make allowance for consumer loyalty in relation to certain foods.

FAIM Methodology

The EFSA / ANS Panel Food Additive Intake Model is a deterministic approach based on the food consumption data available only within EFSA from the full Comprehensive European Food Consumption Database. Because the model includes only summary data it is not possible to estimate total high level intakes from all food sources by summing high level intakes from individual food sources because high level consumers of one food are not necessarily also high level consumers of all other foods. In fact, energy intake considerations make it unlikely that an individual is a high level consumer of more than one food. This subject has been discussed in depth elsewhere and the conclusion reached by the EFSA Scientific Committee and proposed for use with the Comprehensive European Food Consumption Database is that the best approach is to combine high level (95^{th} percentile) intake for consumers only of the food with the highest high level intake with the sum of the population average from all other foods. This is the modelling approach employed in the FAIM model.

Food consumption data

The presentation of food consumption data used within the FAIM model has been discussed in Section 1 of this report. It was concluded there that some of the food categories are too broad to allow the inclusion of usage data specific to particular food applications. The food consumption values were discussed in Section 2 of this report and it was concluded there

was scope for refinement and the exclusion of some excessively high values especially for certain children's datasets.

Additive usage data

The FAIM model also uses additive concentration data as one of the data inputs. These are categorised according to the system described in Section I of the report and two options are permissible:

1. Maximum Permitted use Levels (MPLs) from additive legislation; or
2. Reported use levels from usage surveys.

Whilst there can be only one MPL for a given additive in a particular category of food, actual use levels can encompass a broad range. This is because different types of foods within a category may have different characteristics that require different levels of use. This is best illustrated by the use of colours where a yellow pigment might be used typically at relatively low levels to correspond to vanilla or lemon flavours or at high levels if a mango flavour is applied. Similarly, clear drinks and food products will require far less pigment to achieve the same colour hue as in a cloudy or milky product.

This variation is reflected in the EFSA call for data which requests information about maximum and typical or normal use levels in food. The FAIM model is designed to accommodate only maximum values although normal values could be introduced to investigate scenarios. This would be a way of investigating the effect of consumers being exposed to a mixture of maximum and typical use levels but is a complication not considered in the FAIM instructions.

As a consequence, in its recommended mode of operation the FAIM model will assume that high level consumers are consuming foods containing the maximum level of an additive in all of the high level category of food and also in all food consumed at average levels in the diet. In reality, most consumers will be exposed to a range of concentrations reflecting normal, including maximum, use levels and only individuals showing strong consumer loyalty to a particular branded product (or flavour) are likely to encounter the same concentration all the time. This is likely to introduce some conservatism into the approach.

Main food contribution

The FAIM system provide several tabs reporting main food contribution for an additive in each age category. These are based on the percentage of the total population average intake corresponding to each food category. This is interesting information but of limited value when considering possible risk reduction activities when it is necessary to know which foods are contributing most to high level exposure.

It is possible to identify foods that are contributing to high level total exposures by going to each age group/country dataset in turn and scrolling up and down until the highest is found. It would be preferable if this was an automated process that allowed the main contributor to maximum high level exposures to be rapidly identified.

<u>FCRA methodology</u>

This is an approach that was developed for screening food additives by Food Chemical Risk Analysis on behalf of NATCOL (FCRA – Annex 1). The FAIM method was submitted to the

EFSA ANS Secretariat on 24th June 2011 as a proposed approach for screening potential intakes of food colours. Like the FAIM method it is a deterministic model based on the Comprehensive European Food Consumption Database. The method used to estimate total high level intakes is identical to that used in the FAIM model (combine high level (95th percentile) intake for consumers only of the food with the highest high level intake with the sum of the population average from all other foods).

The FCRA system operates using macros in an MS Excel workbook. The user inserts use values against all relevant FoodEx categories on an input page and the clicks a box marked 'Rank All'. This automatically calculates maximum intake associated with each food category in each age group / country dataset and ranks them in descending order. It then generates a results page containing all the highest ranking data.

Food consumption data

Since levels L3 to L4 of the FoodEx data are unavailable outside of EFSA the FCRA method is based in FoodEx level L2, the highest level publicly available. This means that the coding system within the FCRA system is identical to FoodEx L2 and as a consequence is not ideally matched to additive usage data. This means that there is, for example, only one category for all soft drinks and that desserts and ice-cream are combined into one category.

The food consumption data have been edited following EFSA Guidance to remove data where there were insufficient consumers to make reliable estimates of 95th percentile consumers (ref). This means that for some age group / country combinations there are data gaps for 95th percentile consumption. This particularly affects the younger age groups and results in some very low lower bound estimates for mean and high level intake because of the absence of 95th percentile values. It has less of an effect on upper bounds of mean and high level intake.

Additive usage data

The FCRA approach is capable of making use of typical and maximum use levels for each food category where such data are available. Total high level exposure from each food category is calculated using the following algorithm:

Exposure algorithm

Average intake from each food category	=	Average consumption (all subjects) x 'Typical' use level
High level intake from each food category	=	95th %ile consumption (consumers only) x Maximum use level
Total intake associated with each food category	=	High level from that food category + average intake from all other categories
Maximum theoretical exposure	=	Maximum total intake associated with any food category

In this way the 95th percentile consumer of the food category with the highest 95th percentile intake is assumed to always consume foods containing the maximum concentration. It is then assumed that all other foods contain additive levels that reflect typical or normal use levels. The method has advantages because it presents a more realistic scenario than the FAIM model whilst allowing the testing of maximum use levels with a view to future adoption as MRLs.

Main food contribution

Because of the use of macros in the FCRA model, food categories are ranked and those associated with highest exposures appear at the top of each age group / country datasheet. These are easy to read off and the system could be further developed to generate an automatic report of highest contributors to high level intakes.

FACET methodology

The FACET system is a fully functional probabilistic model based on some of the same European food consumption data sources as the FIAM and FCRA models. The database contains the original food diary data coded according to the FACET system, which has been especially adapted to correspond as far as practicable with the European Commission's food additive classification system (ref). Although capable of running probabilistic exposure assessments this capability is limited by the availability of detailed data on levels of additives in foods. If data on distributions of additives levels are available then the FACET system will make a random selection from these. If only single values are available, such as MRL values, then the system will operate as a distributional model assuming that all foods contain the maximum concentration all of the time.

In addition to allowing distributional data about levels of additives in food the FACET system will allow information about occurrence to be entered. Occurrence data reflect the proportion of foods in a particular category that contain the additive. This information can be obtained from surveys of label information.

One of the difficulties presented by a truly random model is that it may not account for consumer loyalty because consumers do not always select foods on a random basis. FACET overcomes this by including an 'consumer loyalty' option which locks the choice of each individual to the first 'choice' that they make. Each time that individual is subsequently sampled in the probabilistic model they will then always have the same concentration of additive in that food thus simulating loyalty to one product.

Food consumption data

Data available within the FACET system are summarised in Table 1. As with the FAIM and FCRA databases, they are incomplete for all age groups in every country.

Additive usage data

Some additive usage data are pre-loaded into the FACET system. For some additives these are only MPL values from the Regulation, where these exist. However, for a priority list of additives FoodDrinkEurope has collated detailed usage data that include ranges and typical and maximum values. Data may also be added to the FACET system by the user by entering distributional syntax. For example, if typical and maximum values are known but the relative proportion of each value unknown, then the values can be entered as (typical

value, maximum value). The system will then give them equal weighting so that the maximum value is over-sampled leading to a conservative result. This approach has been adopted in the evaluation studies (Section 5 of this report).

Table 5.1. FACET food consumption data.

Age group	Finland	France	Hungary	Ireland	Italy	Poland	Portugal	UK
0 - 1.5					3d diary (e)	*1d recall*		
1.5 - 3					3d diary (e)	*1d recall*		4d diary (w)
3 - 5		7d diary (e)			3d diary (e)	*1d recall*		4d diary (w)
5 - 12		7d diary (e)		7d diary (w)	3d diary (e)	*1d recall*		7d diary (w)
12 - 18		7d diary (e)		7d diary (e)	3d diary (e)	*1d recall*		7d diary (w)
18 - 25		7d diary (e)	3d record (e)	7d diary (e)	3d diary (e)	*1d recall*	7d diary (e)	7d diary (w)
25 - 65	3d diary (e)	7d diary (e)	3d record (e)	7d diary (e)	3d diary (e)	*1d recall*	7d diary (e)	7d diary (w)
65+	3d diary (e)	7d diary (e)	3d record (e)		3d diary (e)	*1d recall*	7d diary (e)	4d diary (w)
								e – estimated
								w – w eighed

Main food contribution

FACET automatically produces reports indicating the relative contributions to total mean exposures and will also provide 95th (or other) percentile intakes from individual food categories. However, it is only capable of performing this at the level of the 18 main food categories and so if an additive is present in more than on sub-category at different use levels then it will be necessary to run the model with and without some sub-categories in a sensitivity analysis to investigate the effect.

The model also provides estimates of precision to assist in the interpretation of the significance of results.

Uncertainty analysis

All modelling approaches have uncertainty associated with them derived from the input data and from the model itself. Unavoidable uncertainties are generally managed by adopting conservative assumptions. However, it is vital to understand the sources, magnitude and effect of uncertainties in order to make a correct interpretation of results.

The EFSA Scientific Committee has published guidelines to provide methods for expressing uncertainties in dietary exposure assessment[8]. The guidelines reflect the complexity of the subject and acknowledge that it is often not possible to provide quantitative estimates of uncertainty. Instead they recommend an initial qualitative approach where the magnitude of each uncertainty is assessed based on its contribution to the assessment outcome.

In the recommended approach the analysis of direction and magnitude of uncertainty are combined into a single measure using plus and minus sign. Plus signs for an uncertainty indicate that it could have caused small (+), medium (++) or large (+++) over-estimation of exposure, minus signs that it could have caused small (-), medium (- -) or large (- - -) under-estimation of the exposure. Some uncertainties are evaluated as potentially causing either over- or under-estimation (e.g. ++/- -).

Some of the uncertainties associated with the FAIM, FCRA and FACET methods for estimating exposures to food additives have been collated into tables following the EFSA Scientific Committee guidelines (Tables 5.2 – 5.4). There are more uncertainties associated with the FAIM model leading to a probable tendency to over-estimate exposures. The FCRA model is similar in most ways to the FAIM model except that it is able to accommodate typical and maximum use levels. This reduces the expected level of conservatism associated with uncertainty.

The FACET model provides opportunities for considerably more detailed assessments using probabilistic models. In the test evaluations (Section 5) the 'Occurrence' option has not been used ans so it is assumed that all foods can contain the additive. The overall effect is a reduced degree of conservatism compared to the FAIM and FCRA models.

[8] European Food Safety Authority, 2006. Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. Request No EFSA-Q-2004-019. The EFSA Journal (2006) 438, 1-54.

Table 5.2. Qualitative evaluation of influence of uncertainties on FAIM method

Type	Source	Cause of uncertainty	Direction & magnitude
Model	Structure	Use of broad food categories	++
		Assumption of use in all foods	++
		Highest plus average method	+
Data	Additive usage data	Use maximum (or single value only)	++
Data	Food consumption	Variations in survey methodology	-/+
		Variation in age ranges	-/+
		Regional vs. national data	-/+
		Correct coding / aggregation	-/++
		Differences in duration of survey	++
		FOODEX categories do not match usage	--
		Some foods have low % consuming	++
		Overall effect	+++

Table 5.3. Qualitative evaluation of influence of uncertainties on FCRA method

Type	Source	Cause of uncertainty	Direction & magnitude
Model	Structure	Use of broad food categories	++
		Assumption of use in all foods	++
		Highest plus average method	+
Data	Additive usage data	Use maximum and typical values	+
Data	Food consumption	Variations in survey methodology	-/+
		Variation in age ranges	-/+
		Regional vs. national data	-/+
		Correct coding / aggregation	-/++
		Differences in duration of survey	++
		FOODEX categories do not match usage	--
		Some foods have low % consuming	++
		Overall effect	++

Table 5.4. Qualitative evaluation of influence of uncertainties on FACET method

Type	Source	Cause of uncertainty	Direction & magnitude
Model	Structure	Use of specific food categories	+
		Assumption of use in all foods	++
		Probabilistic model	-/+
Data	Additive usage data	Distributional data inputs	-/+
Data	Food consumption	Variations in survey methodology	-/+
		Variation in age ranges	-/+
		Regional vs. national data	-/+
		Correct coding / aggregation	-/+
		Differences in duration of survey	++
		Some foods have low % consuming	++
		Overall effect	+

Conclusion

The main properties of the three dietary exposure models considered here are summarised in Table 5.5. The FAIM model provides a basic tool suitable for food additive exposure screening. It will tend to generate conservative estimates of exposure because:

1. The food categorisation system is very broad, leading to the inclusion of foods that do not contain the additive or contain is a lower concentrations;
2. Only single values can be entered to represent the range of possible use levels, leading to the assumption that all foods contain the maximum level at all times; and
3. Food consumption data are summary data only and are based on some short surveys and may therefore include over estimates of long-term consumption for certain foods;

However, because it is quick and easy to use it may have value as a first tier in a tiered exposure assessment system that can be used to eliminate additives where there are no concerns about high exposure.

The FCRA model is very similar to the FAIM model and suffers from the limitation that it is based on the published Level 2 summary data from the EFSA Comprehensive European Food Consumption survey data. This means that the categorisation system is very broad and it also includes data from short-term surveys that probably over-estimate consumption of certain foods. It has the advantage that it is able to use maximum and typical use level data for each food category so that a more realistic model of exposure is generated whilst maintaining a link with maximum use levels for regulatory risk management purposes. Because it is slightly more complex than the FAIM model, it may also have a role in a tiered

approach to exposure assessment. However, it may be better to combine the two approaches.

FACET is considerably more sophisticated then either the FAIM or FCRA models because it uses dairy-based data coded to a high level of detail relevant to food additive usage. It is possible to create estimates of exposure based on individual food consumption patterns in eight countries. It is also possible to simulate consumer loyalty to ensure that the model generates conservative results. Because it takes more time to run, it is ideal for use at the highest level in a tiered dietary exposure assessment system.

Table 5.5. Summary of main properties of dietary exposure assessment models

Property	FAIM	FCRA	FACET
Model type	Deterministic	Deterministic	Distributional / probabilistic
Food consumption data	Summary data from 14 countries and 5 age bands	Summary data from 14 countries and 6 age bands	Diary-based data from 8 countries with flexible age banding
Body weight correction	Individual-based	Individual-based	Individual-based
Coding system	Simple, based on Reg 1129/2011 and FoodEx	Simple, taken from EFSA FoodEX	Tiered, based on Reg 1129/2011
Usage data	Single value per use category only	Typical and maximum for each use category	Single, multiple or distributional data entry possible
Calculation method	Highest 95th percentile + Mean from rest of diet.	Highest 95th percentile + Mean from rest of diet.	Individual intakes calculated for entire population
Consumer loyalty	Automatically applied	Automatically applied	Available option
Main contributor	Mean only	Mean or high level	Mean or high level
Precision	Not included	Not included	Confidence intervals
Uncertainty	Not included	Not included	Uncertainty report available

Section 5 – Case studies

Aim:

Assess status of the FAIM model in a tiered approach to exposure assessment and evaluate the degree of conservatism associated with its use. Approaches to be evaluated would include (1) initial ANS assessment, (2) FAIM model, (3) alternative colours model ('FCRA' model) and (4) FACET. Incorporate usage data from recent EFSA evaluations to illustrate comparisons.

Background

Additive usage data have been assembled from recent EFSA opinions and from industry sources. Where possible, data that included typical or normal and maximum values have been selected to provide a better basis for comparison. The data have been used for illustrative purposes only. They are subject to all the uncertainties outlined in Section 4 of this report and, apart from the original EFSA Opinions, should not be interpreted for risk assessment or risk management purposes.

In the FAIM model the maximum reported usage value (i.e. not the MPL, unless this was the same) has been used as the input data. Where more than one use application corresponds to a single FAIM category (e.g. Fine Bakery wares) then the highest use level has been entered.

In the FCRA model the upper value for typical use levels (where provided) have been used as input for 'typical' values and the highest reported usage values (i.e. not the MPL, unless this was the same) have been used as input for 'maximum' values. Where more than one use application corresponds to a single FoodEx category (e.g. 'desserts and ices) then the highest use level has been entered.

In the FACET model the value for typical use levels and the highest reported usage values have been used as input using distributional syntax. The values are entered as (typical value, maximum value) so that the system will then give them equal weighting. This will result in the maximum value being sampled as frequently as the typical value and so will lead to a conservative result. The option to include 'Occurrence' data has not been selected in order to provide results that are more comparable with FAIM and FRCA. The option to apply 'Consumer loyalty' has been applied to all food categories thus forcing the FACET system to deliver the most conservative assessment. If occurrence data were available (i.e. the proportion of a given food commodity that contains the additive) and consumer loyalty was applied only to foods where this was most likely to occur, then FACET would deliver lower, more realistic results.

Time limitations have made it impossible to provide a detailed analysis of results and in particular the identification of specific foods leading to high intakes. The author apologies for this although these constraints were beyond his control.

Results

Additive A

Data on additive A use levels were taken from the EFSA Opinion of 2010[9]. The ANS Opinion results were based on EXPOCHI data and on summary statistics for UK pre-school children and adults. Results are summarised in Table 5.1.

Additive B

Data on Additive B use levels were taken from Table 5 of the EFSA Opinion of 2008[10]. Intakes in the Opinion were based on UK NDNS data for schoolchildren and adults (high level based on the two highest 97.5th percentiles + mean exposure for other food categories). Results are summarised in Table 5.1.

Additive C

Data on Additive C use levels were taken from the ANS revised exposure assessment 2011[11] Intakes in the Opinion were based on EXPOCHI data and on summary statistics for UK pre-school children. Four scenarios were explored: Flavoured drinks containing 10, 15, 18 or 20 mg/l and all other food categories containing revised MPLs. In this example fixed values were used to represent concentrations in both FCRA and FACET models. Results are summarised in Table 5.1.

Additive D

Data on Additive D were provided by the European Polyols Association and are unpublished. They were included in this exercise because they contain applications where polyols may be used for their sweetening effect at relatively high concentrations in lo-calorie foods or as humectants in the same foods containing sugar, at considerably lower concentrations. With the exception of non-alcoholic beverages, other confectionery and chewing gum, the FAIM model is unable to accommodate these distinctions. The FCRA model has similar limitation but in this case humectant levels can be taken as typical values and sweetener values as maxima. The FACET model offers considerably more flexibility since flags can be set for each food category to select sugar-free products or not. This allows sweetener and miscellaneous use levels to be entered separately. Results are summarised in Table 5.1. It should be noted that the results presented for Additive D relate to chronic exposure averaged over the periods of the food consumptions surveys. More realistic estimates of Additive D exposure should be based on time periods of a few hours that are more relevant to the digestive tolerance end-point.

[9] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Green S (E 142) as a food additive. EFSA Journal 2010;8(11):1851.

[10] Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on the safety in use of lycopene as a food colour. The EFSA Journal (2008) 674, 1-12.

[11] European Food Safety Authority; Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive. EFSA Journal 2011;9(9):2349.

Table 5.1 Results of case study comparisons.

		Assessment Method								
		EFA Opinion		FAIM		FCRA		FACET		
Additive	**Population**									
		Mean	95th / 97.5th	Mean	95th	Mean	95th	Mean	97.5th	
Additive A	Children	0.1 - 1.7	0.4 - 4.0	1.0 - 2.5	1.9 - 3.8	0.43 - 1.46	0.77 - 2.81	0.34 - 0.91	0.91 - 1.80	mg/kg bw/day
	Adults	0.4	1.1	0.4 - 2.0	1.5 - 7.3	0.16 - 0.48	0.36 - 4.65	0.10 - 0.79	0.41 - 3.65	
Additive B	Children	0.22	0.41	0.6 - 1.7	1.5 - 3.0	0.15 - 0.4	0.4 - 1.28	0.10 - 0.16	0.25 - 0.36	mg/kg bw/day
	Adults	0.06	0.75	0.2 - 1.0	0.4 - 1.3	0.05 - 0.15	0.25 - 0.74	0.03 - 0.11	0.11 - 0.41	
Additive C	Toddlers	0.2	0.61	0.1 - 0.3	0.4 - 0.7	0.02 - 0.13	0.02 - 0.25	-	-	mg/kg bw/day
(10 mg/l nab)	Children	0.02 - 0.15	0.08 - 0.39	0.1 - 0.4	0.3 - 0.7	0.02 - 0.13	0.07 - 0.35	0.02 - 0.14	0.05 - 0.36	
Additive C	Toddlers	0.28	0.9	0.1 - 0.3	0.4 - 0.7	0.02 - 0.17	0.02 - 0.35	-	-	mg/kg bw/day
(15 mg/l nab)	Children	0.02 - 0.19	0.11 - 0.53	0.1 - 0.4	0.3 - 0.8	0.02 - 0.17	0.11 - 0.51	0.02 - 0.19	0.07 - 0.53	
Additive C	Toddlers	0.33	1.07	0.1 - 0.3	0.4 - 0.8	0.02 - 0.19	0.02 - 0.40	-	-	mg/kg bw/day
(18 mg/l nab)	Children	0.02 - 0.22	0.14 - 0.69	0.1 - 0.5	0.3 - 0.9	0.03 - 0.20	0.11 - 0.61	0.02 - 0.23	0.08 - 0.63	
Additive C	Toddlers	0.37	1.19	0.1 - 0.4	0.4 - 0.8	0.02 - 0.21	0.02 - 0.44	-	-	mg/kg bw/day
(20 mg/l nab)	Children	0.03 - 0.24	0.15 - 0.76	0.1 - 0.5	0.3 - 1.0	0.03 - 0.22	0.11 - 0.67	0.02 - 0.26	0.09 - 0.71	
Additive D	Children	-	-	0.47 - 1.36	0.92 - 3.47	0.04 - 0.11	1.38 - 3.26	0.03 - 0.13	0.22 - 0.46	g/kg bw/day
	Adults	-	-	0.14 - 0.59	0.62 - 1.69	0.01 - 0.03	0.54 - 1.26	0.03 - 0.06	0.10 - 0.28	
nab - non-alcoholic beverages										

Note: These results have been provided for illustrative purposes only. They are subject to all of the uncertainties outlined in Section 4 of this report and, apart from the original EFSA Opinions, should not be taken as indicative of actual exposures or interpreted for risk assessment or risk management purposes.

Discussion

Each method has uncertainties associated with it. The FAIM model has broad categories (e.g. processed fruits or alcoholic drinks) that cause distortions and does not allow use of typical and maximum use levels. The FCRA method allows incorporation of typical and maximum values but is limited to the published EFSA FoodEx Level 2 categorisation system. This means that some categories (e.g. desserts and ice-cream) are aggregated. FACET has better disaggregation of food categories and allows a full distributional/probabilistic model to be run where we have typical and maximum use levels. FAIM allows some separation of low calorie from regular products (only two categories: 'soft drinks' and 'Other confectionery') whereas FACET allows complete disaggregation.

The differences in levels of conservatism and detailed methodology are reflected in the results. FAIM tends to give higher results followed by FCRA and FACET. This is without using all of the facilities of FACET in particular occurrence data.

Conclusion

Comparison of the results with the original Opinions is confusing because different methods, including EXPOCHI data for children, were used. The FAIM and FCRA methods give similar results but with FCRA method giving approximately half the values provided by FAIM. This is probably because the FCRA model uses typical use levels to calculate 'rest of the diet' values and only maximum use levels for the highest food category.

The FACET model reduces estimates of total exposure by a factor of 2 to 5 against FAIM and FCRA. This is probably because the more disaggregated coding system allows greater precision and the probabilistic model approximates more closely to the true situation.

The results suggest that FAIM and the FCRA methods may be suitable for screening additive intakes to eliminate those where there is no possibility of exceeding the ADI. However, even screening methods need to be designed to give as few false positives as possible. The categorisation system used in FAIM and its inability to incorporate typical use levels with maximum use levels means that it is likely to give misleading results. It would be improved by a refinement of the categorisation system and merging of methodology from the FCRA approach.

A distributional/probabilistic approach such as FACET should be available at Tier 3 when screening methods indicate the potential to exceed ADIs and it is necessary to obtain a more accurate estimate of true exposures.

Overall conclusions

1. The FAIM categorisation system excludes some important Regulation (EU) 1129/2011 and FoodEx categories where additive use levels may be significantly different. This applies particularly to processed fruit and vegetables, confectionery, processed meat, non-alcoholic drinks and alcoholic drinks. The absence of these sub-categories will result in inappropriate use levels being applied across the broader categories resulting in unnecessary over-estimation of intakes.
2. Some FAIM categories contain FoodEx categories that are not relevant to additive exposure. This applies particularly to unprocessed meat, where the number of approved applications is limited apart from the use of colours for health marking. In other cases FAIM and FoodEx categories are mis-matched such as for sauces.
3. A food categorisation system based on the Regulation (EU) No 1129/2011 categories and including relevant FoodEx categories suitable for an additive screening method report is provided (Table 2.1). This system is intended to represent an alternative to the FAIM system in a simple exposure screening model.
4. The Comprehensive food consumption data used in the FAIM model appear to give an overall over-estimation of food consumption that particularly affects younger children when the energy content of foods is assessed.
5. Certain foods within particular population groups appear to be contributing higher energy intakes than would be consistent with long-term consumption, particularly for children. These include fats and oils, flavoured fermented dairy products, snack foods, processed fruit and vegetables, desserts and fine bakery wares, and for adolescents and adults alcoholic drinks. Food consumption data at the 95th percentiles, which largely determine the output of the FAIM model should be tested and validated to exclude data that are not representative of true long-term consumption.
6. The FAIM model will tend to generate conservative estimates of exposure because the food categorisation system is very broad, leading to the inclusion of foods that do not contain the additive or contain is a lower concentrations; only single values can be entered to represent the range of possible use levels, leading to the assumption that all foods contain the maximum level at all times; and food consumption data are summary data only and are based on some short surveys and may therefore include over estimates of long-term consumption for certain foods.
7. The FAIM and the FCRA methods may be suitable for screening additive intakes to eliminate those where there is no possibility of exceeding the ADI. Both methods would be improved by a refinement of the FAIM categorisation system and merging with the methodology from the FCRA approach.
8. A distributional/probabilistic approach such as FACET should be available at Tier 3 when screening methods indicate the potential to exceed ADIs and it is necessary to obtain a more accurate estimate of true exposures.