Screening method for estimating potential intakes of food colours

Introduction

The Dietary and Chemical Modelling group at EFSA has recently compiled a Comprehensive Food Consumption Database which is a source of information on food consumption across the European Union (EU). It contains detailed data for a number of EU countries and covers all age groups. EFSA has not provided access to the database to outside users and so it is impossible to accurately predict potential intakes of food components using the database. However, EFSA has made available some summary statistics from the database which are intended to enable quick screening for chronic and acute exposure to substances that may be found in the food chain[1].

Food additive producers and users need to be able to estimate potential intakes of additives based on available usage data. If intakes appear to exceed ADIs this may be because of inaccuracies in the data and so should trigger additional quality control checks on data before submission. Similarly, additive producers and users need to be able to predict the consequences of altering usage levels in particular food categories on the total potential intake from all foods if there is evidence that intakes may exceed the ADI.

A simple screening model is therefore required that the food industry can use to check potential intakes. However, it is vital that such a tool makes use of all available information so that realistic, yet conservative estimates of intake are produced.

Additive usage levels in food.

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

Food colours are different to many other food additives in that a wide range of usage is required corresponding to different flavours of varieties of food products. 'Typical' use levels were therefore provided to indicate the use level that corresponded to the flavour or variety in most common use. Some of the more intense 'maximum' usage levels tend to correspond to applications that are rarely or exceptionally consumed.

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 that one product simultaneously and that all such products would contain 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.

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

Proposed approach

A deterministic method has been developed that takes full use of the published EFSA Comprehensive Database (CD) summary data. The method is based on a classical model diet approach where the 95th percentile intake (calculated considering only consumers) from each food category is added to the *per capita* average intake from all other foods in the diet to estimate the total intake of high level consumers of each food type[2]. A more conservative version of this approach consists of summing the 95th percentile of exposure for the two categories that are the main contributors with the mean exposure for the other categories[3]. The second more conservative approach has been included in the method so that it can be referred to in situations where it is feasible that a consumer could simultaneously be a loyal high-level consumer of two products, both of which contain the additive at the maximum use level. This extreme worst case is, however, considered to be a very remote possibility for most food additives.

1. For each food category in which the additive is used a corresponding FOODEX category is identified in the Comprehensive Database (CD) summary data. In some cases there is a direct correspondence in other cases the closest description must be identified. There may be some additive use categories where there is no matching category in the CD. However, this is unlikely to occur for foods consumed frequently or in substantial amounts. In every screening assessment a summary of the mapping should be provided.
2. For each relevant FOODEX food category the average *per capita* consumption, 95th percentile consumers only consumption and the % consuming are extracted from the CD summary of chronic bodyweight corrected data and entered into a spreadsheet.
3. For each FOODEX food category a maximum use level (MAX) is identified from the data provided by producers and users. A value representing the upper level of typical usage is also identified (TYPHI).
4. The average intake from each food category (AV INT) is calculated by multiplying the *per capita* consumption by the upper level of typical usage.
5. The maximum intake from each FOODEX food category (MAX INT) is calculated by multiplying the 95th percentile consumers only consumption with the maximum usage level.
6. Total intake corresponding to a high level consumer of each food category who is ‘consumer loyal (HIGH) is calculated by adding the maximum intake from each food to the per capita average from the rest of the diet (Method ‘A’). Total intakes from each food are ranked to identify the food group with the highest total intake.
7. Extreme worst case intakes are calculated by adding the two highest 95th percentiles from each food category to the per capita average from all other foods (Method ‘B’).

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[2] Verger, P. (1995). One example of utilisation of the ‘French Approach’. Paper presented at the ILSI Europe Workshop on Food Additive Intake, 29-30 March, Brussels, Belgium.

[3] EFSA (2008). Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment EFSA/DATEX/2008/01.

<u>Table 1. Illustration of proposed intake screening approach applied to a food colour</u>

Comprehensive Database Food categories				Food consumption			Usage		Intake		
FoodExL1_name	FoodExL2_name	FoodExL1_code	HFoodExL2_code	Mean	P95	Perc_consumers	TYPHI	MAX	AV INT	MAX INT	HIGH
Non-alcoholic beverages (excepting	Soft drinks	A.01.001471	A.13.01	5.4	14.9	92.1%	40	50	0.22	0.75	0.84
Milk and dairy products	Milk based beverages	A.01.000963	A.08.02	1.4	7.4	56.4%	30	50	0.04	0.37	0.64
Snacks, desserts, and other foods	Ices and desserts	A.01.001888	A.20.02	0.2	1.2	54.1%	60	70	0.01	0.08	0.38
Grains and grain-based products	Fine bakery wares	A.01.000252	A.01.07	0.2	1.1	45.9%	35	50	0.01	0.06	0.36
Sugar and confectionary	Confectionery (non-chocolate)	A.01.001310	A.10.04	0.4	1.5	83.5%	25	40	0.01	0.06	0.36
Milk and dairy products	Cheese	A.01.001053	A.08.08	0.5	1.3	98.7%	20	30	0.01	0.04	0.34
Snacks, desserts, and other foods	Snack food	A.01.001878	A.20.01	0.1	0.8	57.4%	30	40	0.00	0.03	0.34
Alcoholic beverages	Spirits	A.01.001561	A.14.06	0.0	0.4	8.4%	35	50	0.00	0.02	0.33
Alcoholic beverages	Fortified and liqueur wines (e.g. Vern	A.01.001546	A.14.03	0.0	0.2	0.6%	35	50	0.00	0.01	0.32
Herbs, spices and condiments	Condiment	A.01.001649	A.16.05	0.1	0.5	75.6%	20	20	0.00	0.01	0.32
Fruit and fruit products	Other fruit products (excluding bever	A.01.000682	A.05.09	0.0	0.3	5.2%	20	20	0.00	0.01	0.32
Fish and other seafood (including ar	Crustaceans	A.01.000919	A.07.04	0.0	0.2	31.1%	15	15	0.00	0.00	0.31
Vegetables and vegetable products	Vegetable products	A.01.000440	A.02.14	0.0	0.0	29.4%	50	50	0.00	0.00	0.31
Fruit and fruit products	Jam, marmalade and other fruit spre	A.01.000657	A.05.08	0.1	0.5	82.9%	2	2	0.00	0.00	0.31
Herbs, spices and condiments	Chutney and pickles	A.01.001672	A.16.07	0.0		0.0%	50	50	0.00	0.00	0.31
Herbs, spices and condiments	Savoury sauces	A.01.001684	A.16.08	0.0		0.0%	50	50	0.00	0.00	0.31
Composite food (including frozen pr	Ready to eat soups	A.01.001856	A.19.10	0.0		0.0%	40	50	0.00	0.00	0.31
Alcoholic beverages	Wine-like drinks (e.g. Cider, Perry)	A.01.001549	A.14.04	0.0		0.0%	25	25	0.00	0.00	0.31
Products for special nutritional use	Food for weight reduction	A.01.001749	A.18.01	0.0		0.0%	20	20	0.00	0.00	0.31
Products for special nutritional use	Dietetic food for diabetics (labelled a	A.01.001771	A.18.04	0.0		0.0%	20	20	0.00	0.00	0.31
Total from all foods									0.31		
				g/kg bw/day			mg/kg		mg/kg bw/day		

Total High Level Intake (method A) = 0.84

Extreme worst case intake (method B) = 1.17

FoodExL1_name	FOODEX food coding level 1 description
FoodExL2_name	FOODEX food coding level 2 description
FoodExL1_code	FOODEX food coding level 1 hierarchical code
HFoodExL2_code	FOODEX food coding level 2 hierarchical code
Mean	*Per capita* average consumption from Comprehensive Database summary data
P95	95^{th} percentile consumers' consumption from Comprehensive Database summary data
Perc_consumers	Percentage consuming from Comprehensive Database summary data
TYPHI	Upper range of typical use level from usage survey
MAX	Maximum use level from usage survey
AV INT	Average *per capita* intake
MAX INT	Intake for consumer at 95^{th} percentile always consuming maximum level
HIGH	Total intake for consumer at 95^{th} percentile always consuming maximum level

Uncertainty analysis

All modelling approaches have uncertainty within 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[4]. 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. ++/- -).

The uncertainties associated with this proposed screening method for food additives have been collated into a table following the EFSA Scientific Committee guidelines (Table 2).

Table 2. Qualitative evaluation of influence of uncertainties on proposed food additive screening 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	+
		2 highest plus average method	+++
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	++

The deterministic method is based on broad food categories and not specific foods in which the additive may be used. It is also assumed that the additive is present in all foods whereas the additive would only occur in a proportion of the supply in reality. The methods used to model high level intake assume that a high-level 'loyal' consumer would

[4] 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.

always consume one or two categories of food containing the maximum concentration. Taken together, these methodological uncertainties are likely to leads to over-estimation of intake and give a conservative result.

Uncertainties that have been identified in the consumption data include variations in survey methodology (including duration of survey), age ranges and national or regional coverage. Weak correspondence between food additive usage categories and the FOODEX coding system may mean that some minor applications are not included in the intake assessment. All of these factors would have a similar effect in any distributional model based on the raw data from the Comprehensive data set and so are not unique to the deterministic method. However, certain foods with a low proportion consuming could be over-represented in the deterministic model if these also happen to be associated with the highest level of consumption. This factor would be automatically adjusted for in a distributional model based on the raw data from the Comprehensive data set.

Conclusion

The proposed deterministic model probably provides a conservative estimate of potential intakes that can be used as a quality control check and to predict the effects of altering use levels. The degree of conservatism should be evaluated against distributional methods based on the raw data from the Comprehensive data set. However, since these data are not available this cannot be done.

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