TECHNICAL REPORT

Food Additives Intake Model (FAIM): comments received from stakeholders and EFSA's views [1]

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ABSTRACT

The Food Additives Intake Model (FAIM) was developed by EFSA to support applicants in the estimation of exposure to a food additive and to harmonise the submission of the related data. FAIM is based on food consumption data from the EFSA Comprehensive European Food Consumption Database. Following the development of the EFSA Food Additives Intake Model (FAIM), EFSA presented the FAIM tool to interested parties i.e. Members States, the European Commission and key industry stakeholders, in order to collect their feedback prior to its publication. During this exercise, all comments received were considered and addressed. The current report expresses EFSA's views on comments provided by the interested parties, including those provided by industry after a four-week consultation period, which came as a follow up of the EFSA "Stakeholders Workshop on guidance for submission for food additive evaluations", organised on 21 September 2012 in Brussels. In addition, it briefly provides a description of the model, its scope and applications and discusses limitations and uncertainties in exposure estimates resulting from its use. Finally, recommendations for further development of the FAIM tool and its applications are presented.

KEY WORDS

food additives intake model, exposure assessment, food additives

[1] On request from EFSA, Question No EFSA-Q-2013-00885, approved on 7 March 2014.

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[3] Acknowledgement: EFSA wishes to thank the members of the Working Group on Exposure Assessment: Nawel Bemrah-Aouachria (until December 2012), Martine Bakker (until April 2013), Jürgen König, Jean-Charles Leblanc, Oliver Lindtner and Christina Tlustos for the preparatory work on this output, and EFSA staff: Davide Arcella, Alexandra Tard and Stavroula Tasiopoulou for the support provided to this output.

Suggested citation: European Food Safety Authority, 2014; Food Additives Intake Model (FAIM): comments received from stakeholders and EFSA's views. EFSA supporting publication 2014:EN-566. 25 pp.

Available online: www.efsa.europa.eu/publications

SUMMARY

The Food Additives Intake Model (FAIM) tool was specifically developed by EFSA, to support applicants in the estimation of exposure to a food additive and to harmonise the submission of the related data. The purpose of the Food Additives Intake Model (FAIM) is to provide a tool for estimating chronic exposure to food additives. It allows the user to estimate the mean and high level exposure to food additives for different population groups from several European countries.

FAIM is based on summary statistics of food consumption data available within the EFSA Comprehensive European Food Consumption Database. The FAIM tool includes food consumption data on children, adolescents, adults and the elderly for a total of 26 different dietary surveys carried out in 17 different Member States.

Following the development of the Food Additives Intake Model (FAIM), EFSA had presented the FAIM tool (including its "instructions for use") to the interested parties i.e. Members States, the European Commission and key industry stakeholders, in order to collect their feedback prior to its publication. During this exercise, all comments received were considered and addressed. The present report compiles and addresses the comments provided by all the interested parties, including those received by industry after a four-week consultation period, which came as a follow up of the EFSA "Stakeholders Workshop on guidance for submission for food additives evaluations", organised on 21 September 2012 in Brussels.

In addition, it briefly provides a description of the model, its scope and applications and discusses its limitations and uncertainties in the exposure estimates resulting from its use. Particular attention is given to issues related to the food consumption data utilised in the FAIM, such as the dietary surveys included, methodology of data collection, reporting of data, estimation of usual intake, and the necessary data checking in order to ensure consistent and reliable results.

Finally, some recommendations for further development of the tool are presented, also taking into account some of the suggestions provided by the interested parties in relation to possible refinements in the food nomenclature.

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BACKGROUND AS PROVIDED BY EFSA

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 lays down a common procedure for the assessment and authorisation of food additives, food enzymes and food flavourings in view of updating the Community lists of permitted substances defined in the corresponding sectoral food laws. According to this procedure, EFSA is requested to carry out a risk assessment of the substances under consideration for inclusion in the relevant Community list following an application or on the initiative of the Commission.

Following a request made by the ANS Panel on 9 March 2010, a self-task mandate for the preparation of a guidance for submission for food additive evaluations was agreed upon by EFSA on 26 March 2010. EFSA requested the ANS Panel to specifically consider the aspects of chemistry and specifications, proposed uses and exposure assessment and toxicokinetics and toxicity of the substance.

In the frame of the guidance[4] for submission for food additives evaluation, prepared by the ANS Panel in 2011 and published on the EFSA website in July 2012, it was anticipated that applicants would be provided with a template to be used for preliminary calculations of the exposure estimates resulting from the use of the substances under evaluation. The FAIM tool was specifically developed, in collaboration with the Dietary and Chemical Monitoring (DCM) Unit, within this guidance, to support the calculation of food additives exposure estimates to food additives and to harmonise the submission of the related data. The concomitant availability within EFSA of the EFSA Comprehensive European Food Consumption Database, built from the most recent national dietary surveys provided by competent organisations in the European Union's Member States, allowed to link the recently implemented EFSA food nomenclature ('FoodEx') with the new food classification system set by the European Commission in the Annex II to Regulation (EC) 1333/2008.

Following the development of the Food Additives Intake Model (FAIM), EFSA has presented the FAIM tool (including its "instructions for use") to interested parties i.e. Members States, the European Commission and following the EFSA "Stakeholders Workshop on guidance for submission for food additives evaluations", organised on 21 September 2012 in Brussels to key industry stakeholders, in order to collect their feedback prior to its publication. All comments received by the industry during a four week consultation period were considered by the ANS WG on Exposure Assessment, and appropriately addressed through letters sent to the industry stakeholders involved in this exercise in February 2013. Furthermore, stakeholders were informed that EFSA will also publish these comments as well as recommendations in a technical report, to be drafted in cooperation, and agreed upon, by FIP and DCM Units. The ANS WG on Exposure Assessment will be invited to endorse these recommendations linked to the possible revisions of the FAIM model in 2014. In addition, the ANS WG on Exposure Assessment has initiated a more general discussion aiming at enhancing further exposure assessment of food additives and aims for an endorsement of the approach by the ANS Panel in 2014.

TERMS OF REFERENCE AS PROVIDED BY EFSA

EFSA asks its Scientific Unit on Food Ingredients and Packaging (FIP) to provide a technical report on the Food Additives Intake Model (FAIM) linked to the EFSA ANS Panel guidance for submission for food additives evaluations. The aim of this technical report will be to describe the scope and the applications of the FAIM tool, compile and address the comments received by stakeholders, as well as to provide recommendations for further development of the tool.

[4] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760. [65 pp.]

CONSIDERATION

1. Introduction

In the frame of the guidance[5] for submission for food additives evaluations, prepared by the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) in 2011 and published in July 2012, it was anticipated that applicants would be provided with a tool to be used for preliminary calculations of the exposure estimates of the food additives. The Food Additives Intake Model (FAIM) was specifically developed by EFSA to support applicants in the estimation of exposure to a food additive and to harmonise the submission of the related data.

The major component of the FAIM tool consists of the food consumption data which are available in the EFSA Comprehensive European Food Consumption Database for 5 different population groups, and expressed as summary statistics within an excel file. Food consumption data are grouped according to the nomenclature from FoodEx classification system which has been linked to the Food Classification System as presented in the Commission Regulation (EU) No 1129/2011[6], part D. Calculation formulas within the file enable the estimation of average and high percentile of exposure to food additives for different population groups across several European countries and per food groups. The template and its supporting documentation ("instructions for use") have been made available on the EFSA website in December 2012[7].

Since the development of the EFSA Food Additives Intake Model (FAIM), EFSA has taken the opportunity of presenting the FAIM tool (including its "instructions for use") to interested parties i.e. Members States, the European Commission and key industry, in order to collect their feedback prior to its publication. The feedback received from the European Commission and the Member States was taken into consideration and some amendments were made in order to address their remarks (Appendix A). In addition, following the EFSA Stakeholder Workshop on the guidance for submission for food additives evaluations, organised on 21 September 2012 in Brussels, a four-week consultation period was provided to industry. All comments received from the European Chemical Industry Council (CEFIC), the European Specialty Food Ingredients Industries (ELC), the European Technical Caramel Association (EUTECA), the European Food and Drink industry (FoodDrinkEurope), the Natural Food Colours Association (NATCOL), the Union of European Beverages Associations (UNESDA) and from the International Chewing Gum Association (ICGA) were considered and addressed in this technical report.

Overall, EFSA recognized that acquiring feedback from all stakeholders has been a constructive exercise, and could serve as a first step for intensifying further exchanges of information and discussions, with the aim of getting a better understanding of the information available for the exposure assessment of food additives as a part of their evaluation by the ANS Panel.

2. Scope and application of the Food Additives Intake Model (FAIM)

The purpose of the EFSA Food Additives Intake Model (FAIM) is to provide a tool for estimating chronic exposure to food additives. The model can be used for the calculation of exposure estimates, both within the frame of the re-evaluation programme set by Commission Regulation (EU) No 257/2010[8] and for new applications. Therefore, this model may be used by industry/applicants, in support of an application, and by risk assessors, as a first step within the a stepwise approach of the dietary exposure assessment process.

[5] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Draft Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760. [65 pp.]

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

[7] http://www.efsa.europa.eu/en/datexfooddb/datexfooddbspecificdata.htm

[8] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27

For the purposes of the evaluation of the food additives by the ANS Panel, two scenarios can be applied, taking into account: (1) the Maximum Permitted Levels (MPLs) of use as set in the current EU legislation and, (2) the levels of use as reported by industry, for food additives already on the market, or as proposed, in the case of new applications or an extension of use of an existing food additive.

When refined exposure assessments are required for the purpose of the evaluation of a food additive, these will be undertaken by EFSA using raw data available (food consumption as well as concentration data) and more refined food categories, where possible.

3. The Food Additives Intake Model (FAIM): comments received by stakeholders

Several comments on the FAIM tool were provided to EFSA, in relation to the food classification, the food consumption and concentration data used in the model and the exposure methodology applied, as well as more specific comments and proposals for further improvement and adjustment of the food nomenclature. In addition, a technical report ("Technical review of EFSA Food Additive Intake Method (FAIM)") prepared on behalf of CEFIC, ELC, EUTECA, FoodDrinkEurope, NATCOL and UNESDA (Tennant, 2012) was submitted, summarising the comments of the above stakeholders.

The main points raised under the general comments related to the conservatism of the model, which, in turn, leads to an overestimation of the exposure to food additives; different aspects were raised, with regards to their influence on the outcomes and the uncertainties of the model, such as the use of broad food categories and single concentration values reflecting only maximum reported usage levels provided by industry. These comments are addressed in the following sections.

Regarding the food classification, all stakeholders in general concurred with the food classification used in the FAIM tool. Specific recommendations made regarding future adjustments of the current food nomenclature are addressed in section 3.2.1., and in detail in Appendix A and B.

3.1. Food consumption data used in the model

3.1.1. Dietary surveys and quality of the food consumption data

The exposure estimates calculated with the use of the FAIM tool are based on summary statistics of individual raw food consumption data available in the EFSA Comprehensive European Food Consumption Database (EFSA Comprehensive Database), which was built from most recent national dietary surveys provided by competent organisations in the European Union's Member States. The FAIM tool includes food consumption data for children, adolescents, adults and the elderly for a total of 26 different dietary surveys carried out in 17 different Member States.

The age groups in the EFSA Comprehensive Database are defined in the following table:

Table 1: Population groups considered for the exposure estimates of food additives

Population	Age range	Countries with food consumption surveys covering more than one day[(b)]
Toddlers	from 12 up to and including 35 months of age	Bulgaria, Finland, Germany, The Netherlands
Children[(a)]	from 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, The Netherlands, Spain, Sweden
Adolescents	from 10 up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	from 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Spain, Sweden, UK
The elderly[(a)]	from 65 years of age and older	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

(a): the terms "children" and "the elderly" correspond respectively to "other children" and the combination of "elderly" and "very elderly" in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

(b): the total number of surveys may be greater than the total number of countries listed, as some countries submitted more than one survey for a specific age range.

The quality of the food consumption data included in the EFSA Comprehensive Database mainly depends on the methods used to collect individual food consumption data at national level. In the Guidance on the use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment (EFSA, 2011a) and in the scientific publication by Merten et al. (2011), the methodologies used within the available dietary surveys and their impact on exposure assessment are described in detail. In order to ensure that the data were transmitted correctly to EFSA, data providers were asked to check preliminary summary statistics produced using the SAS software programme before inclusion of the data in the EFSA Comprehensive Database. Outliers with regards to the amount of consumption were identified and corrected at a later stage.

EFSA is aware of the fact that different methodologies used for the collection of dietary data included in the EFSA Comprehensive database will affect the comparability of results between countries. In this regard, it is indicated in the "instructions for use" attached to the FAIM tool, as well as in the EFSA Guidance on the use of the EFSA Comprehensive database (EFSA, 2011a), that direct country-to-country comparison with respect to consumption levels is not advisable and consequently, that direct comparisons of country-specific exposure estimates should be made with caution.

Within the FAIM tool, the number of consumers reporting food consumption in each dietary survey is provided, per population group and food category. Food consumption values calculated on the basis of less than five consumers are highlighted in red font and users of the FAIM tool should handle these data with caution. Consumption values (and consequently, exposure estimates), corresponding to actual zero (i.e. no consumption of a specific food items is reported) are represented in the consumption data spreadsheets of the FAIM tool by empty cells. Values below 0.05 g/kg bw/day are rounded to zero and appear as such.

The reliability of high percentiles is based on the number of observations available for each specific category, using the methodology described in the EFSA Guidance on the Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment (EFSA, 2011a). Percentiles calculated on a limited number of subjects should be treated with caution as the results may not be statistically robust (EFSA, 2011a).

Food consumption values at the high percentile (95th) were checked to identify cases where these resulted from an insufficient number of consumers. High percentile consumption levels were replaced by consumer-only mean consumption values when the number of consumers was below 60.

3.1.2. Under and over-reporting

It has been observed that under-reporting is an inherent source of uncertainty in food consumption surveys conducted with either 24-hour recalls or individual dietary records (EFSA, 2009). Over-reporting of food consumption has been associated with food frequency questionnaires, while no gross over-reporting was reported with 24-hour recalls or individual dietary records (EFSA, 2009). The EFSA Expert Group on Food Consumption Data suggested that dietary information from individual subjects should not be deleted on the basis of presumed under- or over-reporting assessed with a short-term survey (EFSA, 2009). Under-reporting was assessed in a number, but not all, of the surveys included in the EFSA Comprehensive Database for adults by comparison of individual energy intake estimates with Goldberg cut-off points. In the evaluated surveys, the percentage of under-reporters ranged between 12 % to 37 % (Merten et al., 2011). Under-reporting may lead to an underestimation of mean dietary exposure and of the percentage of consumers of some particular foods, e.g. foods with high fat or sugar content, whose estimation is more prone to under-reporting (Becker, 1999). On the other hand, under-reporting is likely to have less impact on the assessment of high percentiles of consumption (EFSA, 2009).

Misreporting (some subjects reporting the food that they ate in a wrong food category) of food consumption might also occur caused by the lack of standard portion sizes leading to systematic bias.

3.1.3. Usual intake

EFSA is aware of the fact that assessing long-term intake of foods in a given population based on a short-term dietary survey is subject to uncertainty due to within-person variability (EFSA, 2009; Merten et al., 2011). This might inflate the observed distribution of the intake of a given food and lead to an overestimation of extreme percentiles in the observed distribution, particularly in surveys with one single 24-hour dietary recall per subject. For this reason, dietary surveys with only one day per subject were considered not adequate to assess chronic exposure and consequently excluded from the FAIM model.

As survey duration increases, there is an increase in the observed percentage of subjects reporting non-zero consumption for commonly and rarely eaten foods (EFSA, 2011a). A short-term survey duration might therefore result in a possible underestimation of rarely consumed foods when the sample size is small. This is one of the reasons why the food categorisation cannot be too detailed for a tool such as FAIM intended to produce conservative exposure estimates.

A number of statistical techniques exist to translate short-term measurements of intake into estimates of "usual" consumption (EFSA, 2011b); nevertheless, due to their complexity, these can only be used in the framework of a refined exposure assessment. EFSA supported the ETUI ('European Tool Usual Intake')[9] project the aim of which was to compare different methods for estimating the usual intake distribution for episodically consumed foods (Goedhart et al., 2012).

3.1.4. Use of the FAIM to assess energy intake

As a means of a quantitative indication of the degree of conservatism inherent in the FAIM system, Tennant (Tennant, 2012) has evaluated the food consumption data provided in the FAIM by estimating energy intakes associated with each food type. In this exercise, international food composition data were used and average and 95th percentiles from each food category and total energy intake from all foods combined were compared with WHO nutrient requirements guidelines for each age group. Energy content of foods was taken from the UK Nutrient Databank (McCance and Widdowson[10]). According to Tennant (2012), certain foods within particular population groups appear to be contributing higher energy intakes than would be consistent with long-term consumption, and overall there appears to be an over-estimation of food consumption that particularly affects younger children.

[9] http://www.efsa.europa.eu/en/supporting/pub/300e.htm
[10] http://tna.europarchive.org/20110116113217/http://www.food.gov.uk/science/dietarysurveys/dietsurveys/

The food categories used in the FAIM have been specifically developed for the assessment of exposure to food additives and are not particularly suitable for estimating energy intake.

For example, the energy content of the category "Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation" was set to 436 kJ/100 g in the exercise performed by Tennant (Tennant, 2012). However, the energy content for the 210 different food items falling in this food category (as reported by the national data providers) ranges from 113.4 to 581.9 kJ/100 g (mean=254.4; P95=477.2). The same variability of energy content is observed within many other food categories in FAIM.

In a report describing the results of the "Dutch National Food Consumption Survey in Young Children, 2005/2006" (RIVM, 2008), energy intake has been calculated using the most refined food composition data and method currently available, and a statistical analysis has been used to assess habitual energy intake. The 95th percentile for habitual daily energy intake in boys and girls aged 2 to 3 years has been estimated to be 7.536 and 7.186 kJ (480 and 476 kJ per kg bw after the correction for the mean body weight), respectively. Using the FAIM model, high level energy intake among toddlers in the Netherlands was estimated to be 671.2 kJ per kg bw, only 40 % more than the most refined estimate. These results illustrate that the FAIM model is conservative with respect to the food consumption data included in the model, within an acceptable range.

3.1.5. Exposure estimates for food additives calculated using the FAIM tool

The exposure estimates calculated with FAIM provide information on the mean and high level exposures per age class (toddlers, children, adolescents, adults and the elderly), summarised per dietary survey and food category. The approach used for estimating high percentiles of exposure from all contributing food sources is based on the assumption that an individual might be a high-level consumer of one food category only, and would be an average consumer of all the remaining food groups. This method consists of adding the highest high level of exposure from one food category (calculated for consumers only) to the mean exposure values for the remaining categories (calculated for the total population).

Furthermore, the model provides information on the food groups contributing to the total mean exposure (% of contribution per food group and per dietary survey), with focus on the main contributing food groups (> 5 % of total exposure) across the EU countries (range of min-max of % contribution across dietary surveys).

In order to consolidate the use of such tool at a larger scale for the safety of food additives and prior to its use within the EFSA ANS safety assessments and also outside EFSA, a comparative test phase of the FAIM tool has been performed by EFSA using as examples food additives with different technological functions (colours, sweeteners, miscellaneous).

For all examples, comparisons of exposure estimates were performed using the same concentration data for foods and using different levels of food classification for food consumption data (through FoodEx nomenclature). For each additive exposure estimates are done: 1) with the FAIM tool with its exposure calculation formula (food consumption expressed as summary statistics for the food categories used in FAIM, 2) by "computer analysis" where food consumption data are expressed at individual level following the same food categories used in FAIM. For 3 of those food additives, exposure was also estimated by using food consumption data expressed at individual level according to the finest level of detail available in the FoodEx classification system (i.e. FoodEx level 3 or 4). This last scenario is generally called refined exposure estimate in EFSA statements or EFSA opinions since 2011.

The comparisons of exposure results obtained through the FAIM tool and the refined exposure estimate are presented in appendix C for the following food additives:

- Aspartame (E 951), compared with 2013 EFSA opinion[11].
- Calcium carbonate (E 170), compared with 2011 EFSA opinion[12],
- Caramels colours (E 150 a, c, d), compared with 2012 EFSA opinion[13]

For other two food additives, sunset yellow (E 104) and benzoates (E 210-213), results are not presented here because in the framework of the re-evaluation program for food additives, these EFSA opinions are currently under discussion.

The results yielded in both cases were considered as being in the same order of magnitude when using the FAIM classification and of highest magnitude when using the finest FoodEx level of classification (e.g. FoodEx level 3 or 4). Therefore, the ANS WG on exposure assessment[14] and the ANS Panel[15] concluded the FAIM as being a sufficiently conservative exposure model compared to calculation made by "computer analysis" concerning the high level of exposure.

3.2. Food classification/nomenclature

The nomenclature used in the FAIM tool is the one used within the Food Classification System (FCS) presented in Part D of Annex II to the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. The FCS consists of four levels; however, for the sake of simplicity, data at level 2 of the FCS are in general provided within the FAIM. For non-alcoholic beverages, which have been shown to be large contributors to exposure estimates for some food additives in some population groups, the food categories were subdivided at a lower level (FCS level 3). This was also the case for cheeses.

As the food consumption records available within the EFSA Comprehensive Database are codified according to the FoodEx classification system (EFSA, 2011c), for the purpose of the exposure assessment of food additives, the FCS nomenclature was linked to the FoodEx classification system. As for the FCS, the FoodEx classification system is composed of four levels (level 4 providing the most detailed description of food items) besides the original food names. FCS and FoodEx food nomenclatures were linked up to level 4 of the FoodEx, when needed.

Overall, the food nomenclature used in the FAIM consists of 65 food groups. The FCS nomenclature, as well as the food items selected from the EFSA Comprehensive Database (FoodEx) nomenclature to be linked to each FCS food category, are included in the tool for transparency (under "Nomenclature" and "Foods list" worksheets, respectively).

Many exceptions/restrictions apply in the list of the authorised food additives and conditions of use in food categories (Part E, Annex II to the Regulation (EC) No 1333/2008). It was not possible in the current version of the FAIM tool to consider all of the exceptions/restrictions, but the main one ("*energy-reduced or with no added sugar*") was taken into account. Following the initial linkage of FCS-FoodEx categories, further refinement has been made for a few food groups in order to set apart products with sugar from products with sweeteners within the categories of confectionery, chewing gum and flavoured drinks. It should be noted that to take this main restriction into account, the most detailed levels of FoodEx were used in the FAIM tool i.e. up to level 4 or even the original food descriptors.

[11] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2013. Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive. EFSA Journal 2013;11(12):3496, 263 pp. doi:10.2903/j.efsa.2013.3496

[12] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of calcium carbonate (E 170) as a food additive. EFSA Journal 2011;9(7):2318 [73 pp.]. doi:10.2903/j.efsa.2011.2318. Available online: www.efsa.europa.eu/efsajournal.htm

[13] European Food Safety Authority; Refined exposure assessment for caramel colours (E 150a, c, d). EFSA Journal 2012;10(12):3030. [39 pp.] doi:10.2903/j.efsa.2012.3030. Available online: www.efsa.europa.eu/efsajournal

[14] http://www.efsa.europa.eu/en/fipwgs/documents/exposureassessment.pdf

[15] http://www.efsa.europa.eu/en/events/event/120417a-m.pdf

However, the level of detail available in the FoodEx nomenclature did not always match the exact description of the food item according to the FCS. Some foods presented in Annex II to Regulation (EC) No 1333/2008 could not be identified in the FoodEx nomenclature (e.g. products as defined in the food additive legislation were very specific, such as heat-treated milk products vs. non heat-treated milk products). Other food items represent a part of other foodstuffs and are not distinguishable from them in the FoodEx classification e.g. decorations, coatings, fillings (it may, however, be possible to take their contribution to exposure estimates into account through the relevant composite foodstuffs by means of assumptions reflecting their actual presence in the latter). For this reason, these specific food groups are not represented in the FAIM. Overall, the food groups which are not represented in the FAIM tool are as follows: FCS Category 2.3: Vegetable oil spray; FCS Category 5.4: Decorations, coatings and fillings; FCS Category 6.6: Batters; FCS Category 6.7: Pre-cooked or processed cereals. Not considering the above listed foods in the exposure assessment of a food additive in which they are permitted have been considered to result in minor underestimations of the exposure to this food additive.

To take account of this, adjustments in the food nomenclature were made, where possible:

- The FoodEx nomenclature does not allow to differentiate fermented milk products, non-heat-treated after fermentation from those heat-treated after fermentation; therefore, the corresponding food groups 1.2 and 1.3 in the FCS nomenclature were combined into food group '1.23 - Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)' food group in the FAIM tool.

It should be noted that under the FCS some food groups contain up to 11 sub-groups below the FCS level 2 (e.g. the food groups of fruits and vegetables, meat, alcoholic beverages). For this reason, when different maximum permitted levels (MPLs) of use and/or use levels apply within these sub-groups, the highest use level value should be used in the FAIM tool to perform the exposure calculation, except when the product for which the highest value applies is a very specific product (niche product or country specific product, e.g. 'only edible external coating of pasturmas', 'only dulce de membrillo'…).

3.2.1. Proposals received for modifications in the current nomenclature

Some modifications in the FAIM nomenclature were proposed by interested parties (Appendix A and B). Following examination of the modifications proposed, and in consultation with the European Commission (i.e. in relation to FCS food descriptors), the following adjustments in the food nomenclature will be considered in future revisions:

- Fine bakery wares (under FCS category 7.2): separating cereal bars, pastries and cakes and biscuits (cookies) would allow for further refinement.

- Milk-based beverages (included under FCS category 14.1.4): milk-based drinks could also be differentiated as a separate category within the non-alcoholic beverages category, to take into account the fact that for some food additives use levels in milk-based drinks may differ from those in water-based drinks.

- Unprocessed meat (under FCS category 8.1): currently all non-processed meat products are considered in this food category in the FAIM template. However, food additives are mainly used in the following foods: breakfast sausages, burger meat, gehakt and fresh-packed preparations of fresh minced meat, with the exception of some food colours used specifically for hygiene marking of meats; therefore this category could be further refined.

- Alcoholic beverages (FCS category 14.2): wines and beers could be separated from other alcoholic beverages (e.g. spirits) considering their differences in consumption levels and reported usage levels.

- Processed fruit and vegetables (FCS 4.2): Some of the proposals may be considered (e.g. sub-divided dried fruits and jams), while some food groups are not referenced in the FoodEx nomenclature (e.g. dried vegetables, canned products) and therefore cannot be differentiated.

Since some of the above food categories are usually main contributors[16] to the total exposure estimates of several food additives, such modifications will allow further refinement of the exposure calculations for food additives which are authorised in the relevant food categories.

For all other food groups described in Appendix B, the proposed modifications could not be considered for reasons that are described in detail in Appendix B, e.g. because the proposed food category or food items do not exist in the current FoodEx classification and therefore cannot be taken into account at present. Since the FAIM is a model based on food consumption summary statistics (i.e consumption data per major food groups and not per food items), such a model is considered not validated when too many food categories are considered (EFSA, 2011a).

Updating the FAIM tool is foreseen (e.g. when new dietary surveys will become available within the EFSA Comprehensive Database, expected in 2014). An update might also be needed, if further improvements in the nomenclature and/or linkage with FoodEx (Comprehensive Database nomenclature) become necessary. Improving the nomenclature may allow to reflect more accurately the actual usage of food additives and will reduce uncertainties concerning high percentiles of exposure.

3.3. Concentration values

For the purposes of FAIM, MPLs of use as set in Annex II to Regulation (EC) No 1333/2008, and maximum reported use levels as provided by industry are the use levels mainly considered by EFSA in the application of the FAIM in exposure assessments. Concentration data from other sources i.e. analytical/monitoring data could also be considered, where suitable and available.

It should be noted that in some occasions maximum reported use levels provided by industry might not be used in the exposure assessment, taking into consideration additional relevant information indicating that these are not appropriate e.g. limited representativeness regarding market share, in the European market, foods in which these actually apply being very specific (e.g. niche products). Accordingly, maximum reported use levels provided for a food category but corresponding to niche products only (e.g. very specific products eaten in one country) are not taken into account in the exposure estimates for this food category performed with the FAIM tool.

3.4. Uncertainty analysis

Since September 2012, an analysis of the uncertainties influencing the exposure assessments performed by the ANS Panel has been incorporated in the dedicated section of the scientific opinions. A section describing uncertainties was also included in the FAIM "Instructions for use".

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered when using FAIM tool and are summarised below:

[16] food categories which contribute to more than 5% of the total mean exposure

Table 2: Qualitative evaluation of the influence of uncertainties on exposure assessment

Sources of uncertainties	Direction [(a)]
Consumption data: different methodologies / representativeness / under-reporting / misreporting / no portion size standard	+/-
Use of data from food consumption survey of few days to estimate long-term (chronic) exposure	+
Correspondence of reported use levels to the food items in the EFSA Consumption Database: uncertainties on which precise types of food the use levels refer to	+/-
Use of the FAIM tool nomenclature (FoodEx level 2)	+
Occurrence data: maximum reported use levels considered applicable for all items within the entire food category, exposure calculations based on the maximum reported use levels	+
Uncertainty in possible national differences in use levels of food categories, concentration data not fully representative of foods on the EU market.	+/-

(a): + uncertainty with potential to cause over-estimation of exposure; - uncertainty with potential to cause underestimation of exposure.

Overall, the total estimated uncertainty from all the above-mentioned sources would generally lead to an overestimation of the exposure to a food additive, thus providing conservative estimates.

4. Discussion

The Food Additives Intake Model (FAIM) was developed as a tool for estimating chronic exposure to food additives. It allows the user to estimate the mean and high level exposure to food additives for different population groups throughout several European countries. The model also provides information on the food groups contributing to the total mean exposure.

The FAIM tool is envisaged to be employed as a deterministic approach and may be used with all kind of fixed values and not only MPLs or maximum reported use levels. In the future, more appropriate concentration values (e.g. typical use levels[17]) could be also taken into account in the exposure estimates when these are available, and provided that these are sufficiently representative of EU industry practices within EU market. EFSA would consider using the most frequently used use level (typical use level) values instead of the maximum use levels, provided more information is received from the stakeholders e.g. on the usage level in terms of number of foods for which the usage level apply, percentage of the foods in the market share, ….

Nevertheless, it is important to keep in mind that uncertainties exist in the exposure estimates owing to the variability in food patterns (e.g. brand loyalty), in food consumption across the EU population and in usage practices within the EU food industry (e.g. percentage of foods containing an authorised food additive, level of use within ready-to-eat foods (typical or maximum reported use levels). In the absence of reliable refined data (as mentioned above) which would allow EFSA to decrease uncertainties in its exposure estimates figures, sufficient conservatism should be ensured in order to adequately protect public health. This can be achieved by employing conservative approaches when relevant information is missing (for instance, by assuming 100 % brand loyalty of consumers), which is a typical situation for food additives.

A stepwise or tiered approach in which the initial steps rely on conservative methods is commonly used to minimise estimation costs and focus resources on the most important issues for which there is a potential health concern. The stepwise approach to dietary exposure assessment is such that as the accuracy of dietary exposure assessments increases, the cost of collecting adequate data and human resources needed to undertake the assessments also increases.

[17] The terms "typical use level" and "normal use level" are assumed to represent the same meaning. Ranges of values are based on the information received from different industries for different food products that fall into the same food category.

Refined exposure assessments are undertaken by EFSA when required for the purpose of the safety evaluation of a food additive, making use of the raw individual data available (food consumption data from the EFSA Comprehensive database and also concentration data) and use of more refined food categories, if possible.

In order to do so, an agreement between EFSA and the national providers defines the conditions for use of the food consumption data in the EFSA Comprehensive Database. EFSA has the right to use the raw, individual food consumption data for carrying out risk assessments and other scientific analyses within the activities related to EFSA's mandate and a formal authorisation from the data provider must be requested for any other use of the data. Consequently, individual food consumption data are stored by EFSA. Only summary statistics from the EFSA Comprehensive Database are made available to the public on the EFSA website.

CONCLUSIONS AND RECOMMENDATIONS

The FAIM, developed by EFSA initially for applicants, is a tool to enable risk assessors to estimate exposure to food additives as a first step of the dietary exposure assessment. It can be used for the estimation of exposure to a new food additive for which authorisation is requested, for an extension of use of an existing food additive, or the estimation of exposure resulting from the uses of food additives already in the market.

A revision of the FAIM tool is expected following the update of the food consumption data in the Comprehensive Database; new dietary surveys are expected to become available and included in the EFSA Comprehensive Database in 2014.

FAIM nomenclature follows the nomenclature from Annex II to the Regulation (EC) No 1333/2008 generally up to its level 2. Therefore, minimising uncertainties due to broad food groups is recommended. For that purpose, some of the suggestions provided by the stakeholders on modifications in the current nomenclature will be taken into consideration, as discussed in section 3.2.1 for an update of the FAIM tool. This will reduce uncertainties on high percentiles of exposure.

The use of concentration data other than the maximum usage level within the framework of the re-evaluation programme for food additives set by Commission regulation could also be considered.

Among others, recommendations which are expected to decrease uncertainties in the estimation of exposure, and therefore improve the current exposure figures from the FAIM tool and its use, include:

1. A common definition of the representativeness of the data (usage levels and market share data on the products) made available by industry would help to take additional information from stakeholders into account within the FAIM tool.

2. As part of the legal obligation set by Regulation (EC) No 1333/2008, submission of food additives occurrence data from monitoring programmes implemented by Member States should be encouraged. To help this process, a priority list of food additives to be monitored, based on current usages and main foods consumed contributing to theoretical dietary exposure, needs to be set, endorsed by Member States, and planned into a middle-term strategy of monitoring programme coordinated at EU level.

Harmonisation of the collection of occurrence data at the lowest FoodEx level classification should be encouraged by all interested parties under EFSA for the purpose of more refined exposure assessments.

DOCUMENTATION PROVIDED TO EFSA

1. Comments on the EFSA Food Additives Intake Model (FAIM). Submitted by the European Food and Drink industry (FoodDrinkEurope). 31 October 2012.
2. Comments on the EFSA Food Additives Intake Model (FAIM). Submitted by the Union of European Beverages Associations (UNESDA). 1 November 2012.
3. Comments on the EFSA Food Additives Intake Model (FAIM). Submitted by the Natural Food Colours Association (NATCOL). 2 November 2012.
4. Comments on the EFSA Food Additives Intake Model (FAIM). Submitted by the European Specialty Food Ingredients Industries (ELC). 2 November 2012.
5. Tennant D, 2012. Technical review of EFSA Food Additive Intake Method (FAIM). FCRA (Food Chemical Risk Analysis). On behalf of: CEFIC, ELC, EUTECA , FoodDrinkEurope, NATCOL, UNESDA. 2 November 2012. 43 pp. Available online: http://fcra.co.uk/research-development.

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APPENDIX

Appendix A. Comments received from the European Commission and Member States on the FAIM tool and comments from EFSA

SECTION	COMMENTS as RECEIVED	EFSA COMMENTS
General comments	*Requests to include lowest levels for some food groups e.g. in particular for food groups including a large number of products which have sub-categories: processed vegetables, dried vegetables; processed meat. Otherwise, exposure will be overestimated.*	EFSA is aware of the limitation due to the grouping of food groups. However, at this stage, the nomenclature to be used will stay as it is, with the exception of cheeses (difference between unripened, ripened, processed) and juices (vegetable and fruit juices). Further development and detailed nomenclature could be done at a later stage.
	No consideration of food groups 5.4 decorations, coatings and fillings, except fruit based filling; covered by category 4.2.4; 6.6 batters, 8.2.3 casings and coatings and decorations for meat that could lead to underestimation. It is important that underestimations are also shown in the model.	In order to improve the transparency of the exposure estimation results, in the instructions of use the food groups which cannot be taken into account because it was not possible to make the linkage between FCS and FoodEx food classification are indicated (e.g. food category 5.4 decorations, coatings and fillings).
	It would be helpful to see intake results as percentages of the ADI	The suggestion was implemented and the value of the ADI to be considered can be inserted in the apposite cell by the user.
	As some level 2 food categories are quite broad, more advice should be given to applicants regarding which values should be included for reported use levels in the concentration spreadsheet	When several MPLs of use and/or use levels apply within the sub-groups, the highest use level value should be used in the FAIM to perform the exposure calculation, except when the product for which the highest value applies is a very specific product (niche product or country specific product, e.g. 'only edible external coating of pasturmas', 'only dulce de membrillo'…).
Nomenclature/ Food lists	*Clarifications have been proposed by the EC with regards to the correspondence of specific foods within some food sub-categories, e.g. 1.8. dairy products and analogues, 2.2. fats and oils and fat emulsions.*	These have been taken into account within the FAIM food correspondence table.

Appendix B. Proposed modifications received from industries on the FAIM nomenclature and comments from EFSA

ORGANISATION	FOOD GROUP	COMMENTS as RECEIVED	EFSA COMMENTS
FoodDrinkEurope	**1. Dairy products**	*Dairy products: it was suggested that this category should include the sub-category 'other cheese products'*	No such products exist in the FoodEx nomenclature (not distinguishable from others).
FoodDrinkEurope/ NATCOL	**4.2. Processed fruits and vegetables**	*Processed fruit and vegetables: this category 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.* *We understand that the categories included in FAIM are a compromise, however colours in particular may be used in only certain limited products within a category. For instance the category "Processed fruit and vegetables" contains some products that are consumed in relatively large quantities but that do not use colours, and other products such as jams, where colours are used but the quantities consumed are much smaller.*	Some of the proposals may be considered (e.g. sub-divided dried fruits and jams), while some food groups are not referenced in the FoodEx nomenclature (e.g. dried vegetables, canned products) and therefore cannot be differentiated.
FoodDrinkEurope/ NATCOL	**5.2. Other confectionery**	*Confectionery: this 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.* *Another particularly critical category for colours is that of "decorations and coatings" which is included within the general confectionery category however would normally comprise a small proportion of the whole product but contain higher levels of colour.*	A 'decorations and coatings' food category or food items does not exist in FoodEx and therefore these cannot be taken into account at present. Since their consumption might be marginal, they are either taken into account through other products which have decorations or coating such as cake etc. when those are included in the exposure estimate, or they will not be taken into account (as mentioned in the instructions for use). This later option will lead to an underestimation and will be mentioned in the EFSA scientific outputs.

ORGANISATION	FOOD GROUP	COMMENTS as RECEIVED	EFSA COMMENTS
FoodDrinkEurope	**7.2. Fine bakery wares**	*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 apply.*	It is possible to separate cereal bars, pastries and cakes and biscuits (cookies) to allow for further refinement.
FoodDrinkEurope	**8.1. Unprocessed meat**	*Unprocessed meat: include only breakfast sausages, burger meat, gehakt and pre-packed preparations of fresh minced meat (other colour use limited to health marking).*	Currently all non-processed meat products are considered in the FCS food category 8.1. However, food additives are mainly used in the following foods: breakfast sausages, burger meat, gehakt and fresh-packed preparations of fresh minced meat, with the exception of some food colours used specifically for hygiene marking of meats; therefore this category will be further refined. This may require going down to the original food name descriptors within the dietary surveys.
FoodDrinkEurope	**8.2 Processed meat**	*Processed meat: Separate heat-treated meat, pâtés and terrines and cured meat products to allow for variations in use levels.*	
FoodDrinkEurope	**12.6. Sauces**	*Sauces: provides an example of mixing of categories, the consumption of which are not comparable, i.e. ready-to-eat, dehydrated and concentrated products; chilli 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'*	No information on dehydrated, dried, concentrated sauces is available within the FoodEx nomenclature. Within the food category sauces, condiments (e.g. mustard, soy sauce ...), dressings and savoury sauces could eventually be separated but since it would require further data checking (i.e. consumption data with a low number of consumers) whereas this food group is not a major food contributor for numerous food additives, this is not intended to be done as a next refinement.

ORGANISATION	FOOD GROUP	COMMENTS as RECEIVED	EFSA COMMENTS
FoodDrinkEurope/ UNESDA/NATCOL	**14.1. Non-alcoholic beverages**	*Non-alcoholic beverages: use all FoodEx categories (containing fruit, flavoured, colas, etc.) because additive use is linked to flavour, etc.* *The FAIM system is not as refined as the FoodEx categorisation whereby "flavoured drinks" are broken down into sub-categories per flavour. It would be beneficial to introduce these subcategories into the FAIM system in order to refine the exposure assessments on additives that can be excluded from certain sub-categories. For example, the consumption of "cola" products can be excluded from an exposure assessment on yellow colours.* *The category "non-alcoholic beverages" is another category where further refinement is critical for colours as some categories such as cola would only contain a limited range of colours, and the colours used are strongly linked to the flavour.*	Within the non-alcoholic beverages (soft drinks), flavoured drinks are separated from other non-alcoholic beverages. The choice has been made so that flavoured drinks could be further differentiated between flavoured drinks with or without added sugar. Additional distinction within non-alcoholic beverages on the basis of their colour would be more complex since the reporting of the foods is not always detailed enough and consumption data should be interpreted with caution. Moreover, by increasing the number of food groups, assumptions made for the calculation the high level exposure (95th percentile) would not be valid any longer (EFSA, 2011a).
FoodDrinkEurope/ UNESDA	**14.1. Non-alcoholic beverages**	*Non-alcoholic beverages: Include milk-based drinks as a separate category because use levels are different from water-based drinks.* *It would be beneficial to include milk-based drinks as a separate category because use levels of some additives in milk-based drinks are different from use levels in water-based drinks.*	It is possible to separate milk-based drinks to allow for further refinement.
FoodDrinkEurope	**14.1. Non-alcoholic beverages**	*Non-alcoholic beverages: Move A.08.09.004; Oats drink, A.08.09.005; Rice drink and A.08.09.008; Soya drink to1.8 Dairy analogues.*	It has been checked and confirmed with the EC that in the Food Categorisation System these food items fall under category 14.1.4 and are not considered as dairy analogues.
UNESDA	**14.1. Non-alcoholic beverages**	*Regulation (EU) No 1129/2011 distinguishes further product sub-categories that are not included in the FAIM or the FoodEx. These sub-categories (such as dilutables, sports drinks, vegetable protein drinks, barley water etc.) have specific maximum permitted levels for additives that are not applicable to other drink categories. It would again be beneficial if these product categories could be captured in an exposure assessment system to further refine the additive intakes.*	It is not possible to separate dilutables, barley water etc. from other non-alcoholic beverages because these are not referenced in the FoodEx nomenclature.

ORGANISATION	FOOD GROUP	COMMENTS as RECEIVED	EFSA COMMENTS
FoodDrinkEurope	**14.2. Alcoholic beverages**	*Alcoholic beverages: Separate beer, wines, spirits, etc. (see above).*	This food group is broad and wines, beers and spirits could be separated at a later stage. This would result in more food groups, but considering differences in the amount consumed and their usage levels it could be considered to allow for further refinement.
FoodDrinkEurope	**16. Desserts**	*Desserts: Unclear where dairy-based desserts (not yogurt) belong. Unclear where instant dessert mixes belong.*	Dairy-based desserts should be included in desserts (e.g. custard) according to Regulation (EC) No 1129/2011; in fact, they fall under the food category 'desserts' within the FAIM tool.

Appendix C. Results of the comparative tests on dietary exposures performed with food consumption summary statistics and formula calculation of the FAIM template and compared to the refined dietary exposure estimated with the individual raw data in EFSA opinions.

All calculations made either with the FAIM template or within EFSA opinions are performed with the same usage data. Only consumption data vary in the level of detail (from FoodEx level 1and 2 for FAIM as summary statistics and up to FoodEx level 3 and 4 for the EFSA opinion as individual raw data). Mean exposure is calculated on the whole population and high level of exposure (P95) is calculated on consumers only.

Table 1: Aspartame (E 951)

		Adults		The elderly	
		EFSA opinion 2013	**FAIM template**	**EFSA opinion 2013**	**FAIM template**
Scenario using MPLs (incl. table top sweeteners*)	mean	[0.8-8.6]	[2.2-10.2]	[0.5-4.4]	[1.7-5.9]
	high level	[2.5-27.5]	[5.5-27.4]	[1.5-23.5]	[5.0-12.8]

		Adolescents		Children		Toddlers	
		EFSA opinion 2013	**FAIM template**	**EFSA opinion 2013**	**FAIM template**	**EFSA opinion 2013**	**FAIM template**
Scenario using MPLs (incl. table top sweeteners*)	mean	[0.8-4.0]	[2.7-8.4]	[2.3-12.8]	[6.4-19.8]	[3.2-16.3]	[7.5-26.4]
	high level	[2.3-13.3]	[4.8-21.3]	[7.1-32.9]	[10.9-42.9]	[11.8-36.9]	[11.0-46.9]

* a level of 500000 mg/kg was used for the table-top sweeteners (EFSA opinion., 2013)

Table 2: Calcium carbonate (E 170)

			Adults	
			EFSA opinion 2011	**FAIM template**
as food additive	**Scenario 1**	mean	[6-11]	[9-15]
		high level	[11-20]	[13-26]
as food additive + added nutrient source (not incl food supplements)	**Scenario 2**	mean	[14-27]	[23-40]
		high level	[23-62]	[37-80]

			Adolescents		Children		Toddlers	
			EFSA opinion 2011	**FAIM template**	**EFSA opinion 2011**	**FAIM template**	**EFSA opinion 2011**	**FAIM template**
as food additive	**Scenario 1**	mean	[8-19]	[11-25]	[13-28]	[20-35]	[14-29]	[19-37]
		high level	[14-30]	[16-37]	[23-48]	[32-59]	[27-57]	[26-61]
as food additive + added nutrient source (not incl food supplements)	**Scenario 2**	mean	[24-43]	[35-65]	[33-75]	[56-104]	[37-84]	[64-120]
		high level	[41-75]	[58-107]	[48-136]	[80-189]	[65-137]	[82-175]

Table 3: Caramel colours (E 150 a, c, d)

		Adults		The elderly	
		EFSA statement 2012	**FAIM template**	**EFSA statement 2012**	**FAIM template**
Caramel E 150a	Mean	[6-18]	[6-22]	[4-12]	[3-12]
	High level	[16-42]	[18-54]	[13-32]	[12-27]
Caramel E 150c	Mean	[10-43]	[33-97]	[6-30]	[26-72]
	High level	[27-151]	[80-363]	[14-82]	[77-179]
Caramel E 150d	Mean	[9-36]	[32-96]	[6-22]	[22-71]
	High level	[26-101]	[78-382]	[19-60]	[74-175]

		Adolescents		Children		Toddlers	
		EFSA statement 2012	**FAIM template**	**EFSA statement 2012**	**FAIM template**	**EFSA statement 2012**	**FAIM template**
Caramel E 150a	Mean	[6-24]	[10-25]	[15-39]	[17-51]	[11-45]	[12-44]
	High level	[16-56]	[21-58]	[36-81]	[33-89]	[32-79]	[35-81]
Caramel E 150c	Mean	[9-33]	[31-67]	[20-56]	[52-109]	[10-60]	[56-95]
	High level	[20-86]	[44-306]	[43-97]	[86-241]	[36-106]	[101-170]
Caramel E 150d	Mean	[8-44]	[28-93]	[19-62]	[43-149]	[11-86]	[55-114]
	High level	[21-122]	[46-330]	[49-136]	[76-277]	[38-127]	[105-237]

* for all 3 caramel colours, the maximum reported usage level made available to EFSA was for some spirit drinks. Considering that these beverages are substantially less consumed compared to other beverages in the group and in order to avoid a large overestimation, decision was taken to use the level of beer (2nd maximum reported use levels made available to EFSA) for the whole food category 14.2.

GLOSSARY AND ABBREVIATIONS

ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
Comprehensive Database	EFSA Comprehensive European Food Consumption Database
EFSA	European Food Safety Authority
FAIM	Food Additives Intake Model
FCS	Food Categorisation System presented in the Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) 1333/2008
FoodEx	Food classification and description system for Exposure assessment
MPL	maximum permitted level