**Executive summary:**

Background: The original concept behind FACET was the creation of a food chemical exposure surveillance system, sustainable beyond the life of the project to meet the needs of EU regulatory authorities in the protection of consumer health. At the outset, there were a number of bottlenecks in exposure assessment. These included access to national food consumption databases, difficulty with food categorization, limited knowledge on food chemical occurrence, lack of data on food chemical concentration and on packaging substances. FACET was designed to address all of these issues with regard to the specific concerns of flavourings, food additives and food contact materials.

Main Results: The major achievement of FACET has been the creation of a publicly available exposure assessment software system. Validated software for deterministic and probabilistic modeling of food chemical intake has been developed. Additional important developments in the project include the establishment of a migration modeling framework for packaging materials into foods, the construction of a tiered food intake database with an integrated harmonized food categorization system and the collection of extensive concentration data for additives, flavourings and food packaging migratory compounds. For flavourings, a total of 41 substances were selected. Concentration data were also collected for natural occurrence of the target substances. Furthermore, analytical investigations for certain flavouring substances in foods have been conducted. In relation to food additives, 32 priority additives were established by the additives and industry questionnaires for providing additives usage levels were developed. Criteria for these priority additives included high risk additives (additives for which the theoretical estimated intake is higher than the ADI in the first approach), additives with or without ADI, additives used quantum satis or with maximum levels, and certain target additives selected or who had their ADI recently modified. For food packaging, data collection on the chemical composition of food packaging materials along with information on the extent and conditions of use was undertaken. The inventory list contains 6,475 substances that are either single substances or are defined or non-defined mixtures of two or more substances. A new in silico QSAR approach has been developed,
validated and used to evaluate the toxicological significance of exposure to packaging substances.

Expected impact: FACET will constitute a perfect tool for post market monitoring since it reflects the real exposure of a targeted population to a food chemical, taking into account the variability of concentration and the real occurrence for each food category. The overall impact of FACET will be evident at a number of levels including protection of the consumer, fostering innovation in the food chain, driving the scientific approach, influencing international food regulatory affairs and through a focused risk management approach.

Project Context and Objectives:

The concept for the FACET project originated in an attempt to harmonise methods and to provide a scientific standardized approach for food chemical exposure assessment in Europe. Prior to the FACET project, efforts to monitor exposure to food chemical intake tended to be orientated toward specific groups of chemicals in isolation. The FACET project draws on the scientific expertise in the three areas of food additives, flavourings and food contact materials together with expertise in food intake, exposure assessment methodologies and software development to deliver a state-of-the-art tool that, for the first time, meets the needs for delivering reliable food chemical exposure assessments. Contemporary food supplies contain a vast range of chemicals. Food chemical risk assessment consists of four stages, hazard identification, hazard characterisation, exposure assessments and risk characterisation.

At the outset of the FACET project, the Science and Technology (S&T) objectives were as follows:
1. To record occurrence levels of targeted chemicals in representative regions of the EU food supply.
2. To create a database of targeted food chemical concentrations in foods, working closely with the food and packaging sectors, and the regulatory authorities.
3. To establish a migration modeling framework for complex packaging materials into foods under real conditions of use to deliver realistic concentration estimates for consumer exposure modeling.
4. To construct a tiered food intake database aimed at foods which are relevant to the target food chemicals.
5. To develop a PC based, publicly available software
6. To build new databases, populate them with the data generated by the project and to estimate exposure assessment using a probabilistic model.

Additives Work-Package: Objectives

- To propose a methodology for the codification of the national dietary surveys appropriate for EU exposure assessment to foods additives
- Selection of high priority food additives to be studied for exposure assessment
- Preparation of the sub-workpackages on levels of food additives in foods
- To collect information on real usage levels for the high priority food additives defined previously
- Guidance to exposure assessment and to the development of dietary surveys to take into account the necessary information for food additives intake surveillance

(b) Flavourings Work-Package: Objectives

- To develop a database of concentration levels for a set of flavouring substances that represent the 2,700 currently on the market and to assess the uncertainty of occurrence and concentration data based on analytical data
- To provide specific guidance in relation to flavouring substances, i) for the collection of data during the occurrence survey, ii) for the categorization of food products in the food consumption databases, and iii) for the development of models of dietary exposure.

(c) Packaging material migratory substances Work-Package: Objectives

- To obtain information on the chemical composition of food packaging materials along with information on the extent and conditions of use, that will allow migration levels to be assigned to food consumption data using the tools developed.
- To establish a verified modelling tool for mono and multi-layer packaging materials for migration into foods under actual conditions of use in order to deliver reliable concentration estimates for use in consumer exposure modelling.
- To provide a validated Quantitative Structure Activity Relationship tool to estimate the toxicity of Food Contact Substances solely from their molecular structure in order to evaluate their safety based on exposure estimates.
(d) Food chemical occurrence data Work-Package Objectives:
- To construct a database on the occurrence of selected food additives, food flavouring substances and food contact materials in representative regions of the EU

(e) Food chemical concentration data Work-Package Objectives:
- To provide a database on the likely technological use of selected food additives in targeted foods
- To populate database with additive concentration ranges

(f) Food intake data Work-Package Objectives:
- To compile a database on food intake across geographically representative regions of the EU based on existing databases
- Newly created targeted food frequency questionnaire studies for specific EU countries where food consumption data limited

(g) Regional modelling Work-Package Objectives:
- To develop suitable food grouping systems and a modelling framework for estimating consumption for the defined food groupings for all EU member states, and test the method with known data sets.
- To obtain new targeted food frequency questionnaire data to validate the predictions of the model and finalise the food consumption database suitable for deterministic or probabilistic modelling.

(h) Exposure Modelling Work-Package Objectives:
- To develop practical yet innovative alternatives to the current simplistic and criticised first-tier exposure models in each area: flavourings, additives, and packaging
- To validate a methodology and construct a tool and data set that will allow robust food safety exposure assessments for the European population into the future.
- To provide an online system for data collection and collaboration for the project.
- To validate and refine the models developed

Project Results:
(a) Additives

There are some basic principles for the assessment of exposure to food additives. The first is that any assessment of exposure should begin with crude screening methods where worst case assumptions are made. (e.g. the "Budget method"). Where such crude screening methods indicate that the reference Acceptable Daily Intake (ADI) value will not be exceeded, then the process ends. Otherwise one moves to the next step in this tiered approach i.e. Tier 2. In this approach, the intake of the target food for each individual is multiplied by the maximum permitted level for each eating occasion of that target food and the sum of all such target foods for each individual is computed. Again, if the ADI is seen to be exceeded then a move to a more refined Tier 3 is undertaken, whereby the intake of each food for each eating occasion is multiplied by the actual concentration level of the target additive in each food at a category level.

The present project has extended the state of the art in the assessment of consumer exposure to food additives. The use of a specific categorization system has improved the level of refinement in the calculations, as the addition of occurrence data and the use of a distribution of concentrations (using a probabilistic Monte Carlo simulation). The first step has been to create a specific food codification system, which avoids generalizing concentration value to foods that don't belong to the same regulated food category. Once this system created, validated and improved, the dietary surveys of 8 countries (Finland, France, Hungary, Ireland, Italy, Poland and Portugal) have been codified through a specially designed web interface and the food categories harmonized. The codification system developed for additives includes a table with about 470 categories of food items and a detailed document which describes the definitions of the different food categories. These food items have been classified in order to make the work of codification as logical as possible. As some additional information was needed in order to assess the intake of additives with more accuracy, a complementary system of flags was developed, in order to specify additional data useful for the codification for additives but also for flavourings and food contact materials. The state of the product (fresh, frozen or canned) has been specified, since this information is necessary for some categories of food (fruits and vegetables, meat, fish. as for those kinds of products, additives used depend directly
of the process it has gone through), as the nutritional status of the product (sugar or energy reduced, low fat etc). Additives present in sausages’ casings or cheeses’ rind, as additives present in fillings or coatings of bakery wares, have also been taken into account.

A guidance document for the codification of food items for additives was developed to explain the system of codification developed for additives as a whole (including the complete list of food categories with linked definitions). The guidance also gives specific instructions to database managers who conducted the coding of their databases in line with the proposed classification system.

(b) Flavourings

In practice, the procedure for the safety evaluation of flavourings integrates information on intake from current uses, structure–activity relationships, metabolism and toxicity. One of the key elements in the procedure is the adoption of the Threshold of Toxicological Concern (TTC) principle. The reliability of intake estimates on the basis of the default approach based on poundage data (MSDI) is difficult to assess. EFSA therefore decided to assess dietary exposure to flavourings with two methods: the MSDI and a method based on reported use levels in food (mTAMDI), and they concluded that for all flavouring substances more reliable exposure data are required. The collection of more direct information and the development of an exposure model would reduce the uncertainty in exposure assessment. The results of FACET will allow a significant reduction in the uncertainty in exposure assessment of flavouring substances.

The present project will extend the state of the art in the assessment of consumer exposure to flavourings. FACET has developed a tool which can efficiently perform exposure assessment on all flavouring substances and a refined exposure assessment based on detailed data for 41 substances. Similar for food additives, a suitable food categorization system for flavourings was developed. A database on flavouring substances (ca. 2500) with reported use levels from different sources was developed: International Organisation of the Flavour Industries (IOFI/JECFA 2006, IOFI/JECFA 2007, IOFI/DGSANCO 2007, IOFI/ECFA 2010 and IOFI/FACET 2010), European Flavour and Fragrance Association (EFFA), Flavour and Extract Manufacturers Association (FEMA), Council of Europe (CoE) and Young). For each substance the information included in the database is related to: (i) its main characteristics (Flavls No.; Flavls name, synonyms, chemical group, molecular weight, etc.), (ii) the estimation of dietary exposure based on screening techniques: MSDI based on poundage data and TAMDI, mTAMDI, SPET based on use levels from different sources.

Specific guidance for the applicability of the categorization system to foods and beverages consumption was provided. In collaboration with WP5, 18 major food categories common to all chemical groups were identified. Within this coding system, WP2 agreed to adopt the specific categorization system prepared for additives according to the 2nd (sometimes 3rd) level of categorization. From the 3rd and sometimes 4th level a specific categorization system was created for flavourings. For fruit the category system is different from that of additives from the 1st level. Moreover, to identify the presence of flavourings in a product ‘flag’ fields were created with the list of all ingredients/tastes of interest in relation to the 41 target flavouring substances. The flags are additional variables to be assigned to food items present in national database consumption. Specific guidance for the selection of food categories and processed food products that may contain flavouring substances to be included in the ‘occurrence survey’ was provided.

The three food categories and sub-categories specifically for flavourings were:
- Non alcoholic beverages: fruit based drinks (containing less than 70% fruit juice)
- Baby foods: infant biscuits, grow up formula, infant fruit puree, infant cereals
- Dairy products: yoghurts.

To select these categories, special attention was given to products with flavour provided by one specific substance (character impact compounds) the presence of which can be easily recognised from the name of the product, and to food categories that cover representative uses of some flavouring substances and to baby foods.

Analytical determinations in products present on the market to assess the uncertainty of occurrence data and concentration data were conducted:

Earl Grey Tea: Linalyl acetate was chosen as a first example from the list of 41 target substances to determine uncertainties in reported concentration levels. This flavouring substance is one of the major constituents of bergamot-flavoured tea (e.g. Earl Grey Tea). A rapid method for isolation and quantification by capillary gas chromatography was developed. The established approach also allows the analysis of linalool, limonene, terpinene and β pinene, terpene constituents of bergamot oil and the respective flavoured teas. The contents of these flavouring substances were determined in 90 Earl Grey teas purchased in ten countries of the EU. Mean, median and 97.5 percentile contents of linalool and linalyl acetate were calculated and the frequency distributions of these flavouring substances in teas were determined. Statistically significant differences were assessed in the light of the country of purchase and of the typology of the products, i.e. factors such as international/national brands, private label brands or not assignable brands sold in speciality tea-
Forest Fruit Teas: In order to extend the data elaborated for Earl Grey teas, contents of flavourings substances and their transfer rates upon hot water infusion were determined in a further group of flavoured teas. Four "forest fruit teas" from different brands were analysed regarding the occurrence of flavouring substances. Fourteen compounds were shown to be present in all four teas and were selected for further analyses. They comprised five of the target substances selected in the FACET project: a-ionone, benzaldehyde, raspberry ketone, vanillin and isoamyl acetate. In addition, β-ionone, 2-methylpropyl acetate, 3-methylbutyl acetate, (Z)-3-hexenyl acetate, (Z)-3-hexenol, benzyl acetate, β-damascenone, undecalactone, eugenol and methyl isoeugenol were chosen.

Fennel Tea: An analytical method for quantification of estragole in fennel teas was developed and validated in order to determine the uncertainty in reported concentration levels regarding this target substance in this food. This substance/food item combination was chosen taking into account flavouring substances present in foods and beverages particularly consumed by children and the safety concern regarding dietary exposure to estragole due to the consumption of fennel tea by infants and children.

Other foods: Qualitative analytical determinations (about 50) were carried out in order to preliminarily evaluate the uncertainty of occurrence of some target flavourings in specific food products: vanillin in baby foods (such as infant formula, infant cereals, infant cereals with milk, biscuits), raspberry ketone in forest fruits-flavoured yoghurt, citral in lemon-flavoured beverages, and others.

Models to assess the potential exposure to the flavourings substances were developed in conjunction with the software developers. In order to implement the model on exposure to flavouring substances, the following data sets were finalized:

For flavourings added to food:
Five tables were built to link the data sets of the different sources of use levels to the food consumption data. Moreover, other tables of linkage were built to merge the use levels data to the standard food categories of the screening method TAMDI, mTAMDI, APET and
For flavouring naturally occurring in food:
Data set of concentration as natural presence: this data set provides natural occurrence data for 28 out of the 41 target flavourings, 620 items with quantitative data on flavourings naturally present were inserted. It was also updated with the correction factors used to transform the concentration measured on the part of a product to the food as consumed.

Data set of food items with ingredients containing natural flavourings: this data set provides the minimum and maximum proportion of the ingredient naturally containing a flavouring substance in food items available on the market in the EU (e.g. minimum and maximum proportion of strawberry in strawberry yogurts). It was provided for 193 FACET food categories for a total of 1581 possible combinations of food item and flag.

Delivered by the Flavourings Work-package:
- A report including a database of reported concentration levels of target flavouring substances in food and the assessment of uncertainty of occurrence and concentration data based on analytical data.
- A guidance document for the collection of data within the occurrence survey and for the categorization of food products in the food consumption databases, in relation to flavouring substances.
- A guidance document for the development of models of dietary exposure to flavouring substances.

(c) Packaging material migratory substances
Since the beginning of the harmonisation of legislation on food packaging a conservative approach has been applied by the European Commission, by EFSA, and by the DG-SANCO Scientific Committee on Food that pre-dated EFSA. This process has been based on potential dietary exposure and on assumptions about migration. This conservative approach assumes that every EU citizen consumes 1 kg of packaged food each day over a lifetime and this food is always packaged in the same material that releases the substance at the maximum concentration legally permitted. A consequence of this default exposure model is that the average consumer will be well protected. However the approach contains several uncertainties which have to be addressed.

An accurate estimate of actual dietary exposure to migrants from food packaging depends on knowledge of:
(a) the packaging materials used;
(b) the occurrence of different chemicals in these packaging materials;
(c) migration concentrations into the packaged foods; (d) consumption of the affected foods, plus
(e) a means to combine this information into reliable estimates of exposure.

Furthermore, there also needs to be a toxicologically-based reference value against which the exposure is compared, to decide if there is an acceptable margin of safety or if the level of exposure presents a risk.

The present project has extended the state of the art in the assessment of consumer exposure to food packaging migratory substances. A database of the chemicals that are likely to be contained in different packaging materials used across Europe has been created during the project. A comprehensive European database on food packaging usage patterns was established for the first time. FACET has developed a scientifically-based classification of foods according to their migration behaviour, to support compliance testing of food packaging and to assist help derive realistic migration values for exposure estimation. FACET has conducted migration research to derive fundamental partition and diffusion parameters to describe the migration process for packaged foods. FACET has developed a mathematical modelling tool to estimate migration from packaging materials into foods under real conditions of use, with both deterministic and probabilistic outputs for exposure estimates. A new in silico QSAR approach has been developed, validated and used to evaluate the toxicological significance of exposure to packaging substances.

Migration Modelling Tool:
Full coverage of consumer exposure to contaminants from FCMs based on analytical determination and market surveys is impossible. Migration from packaging components into food during filling and storage follows well known physical laws and hence is predictable. Migration modelling is based on two major factors: (i) the kinetic factor (the diffusion constant of a migrant in the packaging material) and (ii) the thermodynamic factor (the partition coefficient of a migrant between the food packaging (P) and the food or food simulant (F) Kp/F). For the migration model, approximately 30 food categories, 20 model migrants, and 3 representative food contact plastics were selected. The 30 food categories were selected based on their solubility and diffusion properties. The 20 migrants were selected to include a range of chemical structure, polarities, molecular weights. In addition to the three representative polymer types (LDPE, PET
A large amount of experimental work was conducted in FACET to determine partition coefficients between polymer and food and to derive diffusion coefficients in food, at given temperatures. To derive the data required to determine partition coefficients between different polymers, a number of kinetic studies were carried out. In a first step an appropriate selection of materials (LDPE/PA/LDPE), migrants (BP, DPBD, UVOB) and test conditions was established. First, kinetic studies were performed. In further work migration experiments and literature surveys were extended to derive the modelling parameters needed for different plastic materials as well for materials such as paper/board, coatings, adhesives, printing inks. In total this extensive and highly innovative work gave adequate coverage of all the 247 material types by a process of clustering. In the same way, the Tier-3 FACET food descriptions were clustered so that they could be represented by one or more (e.g. composite foods and ready-meals often needed two or more) of the 30 standard migration foods and then their partition behaviour was represented as a percentage ethanol-water equivalency. Because of the distribution type inputs to the migration model a probabilistic modelling technique was implemented. The output in terms of concentration distributions in foods have been linked with and fed into the probabilistic exposure model in the final software. A specific software for the FACET project called "Aptaufit" - was developed by Partner 9 (FABES) and Partner 18 (INCDTIM). This software calculates diffusion coefficients Dp's with the FABES-formula. New processing algorithms were written to speed-up the numerical solution of the migration equations so that the calculations could be performed on the PC of the end-user of FACET, in reasonable time.

Quantitative Structure Activity Relationship (QSAR) tool:

To ensure the safety of food packaging, it necessary to consider the potential toxicological hazard of any migrating species, the resulting levels in foodstuffs, and the quantities/frequency of the foods consumed. Toxicological testing of chemicals on animals is a very costly and time-consuming process and is also contrary to policies of the OECD nations. In recent years, great strides have been made to improve the quality and reliability of toxicological assessments derived from computerised models based on Quantitative Structure Activity Relationship (QSAR). One task within the FACET project was concerned with filling gaps in the toxicological data of migrating species using computer-based (in silico) predictive toxicology techniques to lead to a better informed risk assessment. No single in silico model can give an unequivocal prediction of different toxicological endpoints, and the OECD recommended approach is to use a "weight of evidence" approach, in which the different predictive tools that are available are used to arrive at a consensus prediction of a particular endpoint.

The study was carried out on a set of 76 food contact substances taken from the FACET inventory list. These comprised 47 individual substances (either single substances or with only simply isomerism) plus 29 complex mixtures (so-called defined or non-defined mixtures in EFSA terminology) that nevertheless are still categorised as each being just one food packaging substance. They included components of inks and polymers used in packaging, for which significant migration was known or believed to occur. The single substances could be dealt with as such (n=47) whereas a total of 97 analogous substances were selected to represent the mixtures (n=29) meaning that on average each mixture needed 3 individual representative substances to describe it. So in total 144 substances were evaluated by in silico methods. Based on discussions with FACET partners, the following endpoints were chosen for in silico assessments: Acute toxicity (rat oral LD50); Carcinogenicity; Mutagenicity; Reproductive/ developmental toxicity; Skin sensitisation. In addition, a series of structural alerts were used to indicate moieties in the target substances which are known to give rise to a toxicological concern related to the endpoints above. Also the Cramer classification of each substance was obtained as an indication of the overall level of concern, as this index is used as part of the Threshold of Toxicological Concern (TTC) approach.

The results of the assessments were used to develop a ranking scheme of the chemical migrants to assist in decisions regarding further toxicological testing or continued use in the food industry. In addition, a database of the supplied compounds has been prepared to allow integration into stakeholders' copies of the OECD QSAR Toolbox for further analysis and use as tools for prediction of toxicity of related but untested compounds. A workflow has been derived to aid end users in making reliable validated predictions from a range of freely available QSAR and SAR tools.

(d) Food chemical occurrence data

If a chemical is legally entitled to be present in a food, this does not necessarily mean it always will be (Lowik, 1996). Therefore, the inclusion of chemical occurrence data into the dietary exposure assessment will refine results, as only foods containing the chemical being investigated are selected for inclusion in the assessments. All packaged labelled foods within the EU are legally required to declare the use of additives and/or flavourings in that branded food item (EC, 2000). Therefore, food ingredient databases are proposed as useful tools in the overall scheme of routine monitoring of food chemical and additives in the E.U (Nutriscan, 1994). Only a few food ingredient databases are currently in existence in the E.U. These food ingredient databases investigate nutrients, ingredients, additives, added flavourings, ingredients that contain naturally present flavourings (spices, herbs, vanillin, etc.) and
packaging material in contact with the foods.

The present project has extended the state of the art in extending knowledge of food chemical occurrence by establishing an agreed format for a harmonised database on food chemical occurrence. Protocols for populating this database across different regions of the EU for food product label information and packaging data have been established. The chemical occurrence database was created in MS Access complete with data on greater than 3800 products from 8 partner countries (Ireland, UK, France, Italy, Finland, Poland, Hungary and Portugal).

For ensuring a standardised approach for product selection across the participating centres and for the ease of data entry into the database, several guidance documents were finalized – these included a document on the use of market share data, a document on data entry into MS Access database, a document on identification of packaging materials and recommendations on photographing packaging components, and a guidance on preparation and sending packaging samples to the relevant partners for further analysis.

Fruit and vegetables (canned): A total of 376 products were purchased for this food-group. This food-group specifically targeted canned or jarred fruit and vegetables imported to the respective domestic markets from outside the EU. The number of products purchased between the eight countries ranged from 13 to 83 (Finland = 59, France = 24, Hungary = 83, Ireland = 43, Italy = 13, Poland = 26, Portugal = 45, UK = 74).

Sauces: A total of 107 products were purchased for this food-group. This food-group specifically targeted sauces in cans or glass jars with metal lids that were imported to the respective domestic markets from outside the EU. The number of products purchased between the eight countries ranged from 0 to 29 (Finland = 29, France = 0, Hungary = 27, Ireland = 9, Italy = 1, Poland = 9, Portugal = 8, UK = 24).

Desserts: A total of 441 products were purchased for this food-group. The food-group was divided into a number of sub-food-groups – yogurt, ice-cream, other desserts: dairy based, egg based or soy based, chilled or ambient, ready to eat, custard, Catalan cream or crème brulée, "Crème Anglaise", mousses and soy based dessert. The number of products purchased between the eight countries ranged from 29 to 122 (Finland = 59, France = 122, Hungary = 65, Ireland = 34, Italy = 47, Poland = 29, Portugal = 56, UK = 29).

Non-Alcoholic Beverages: A total of 506 products were purchased for this food-group. The food-group was divided into a number of sub-food-groups: fruit based drinks, other soft drinks and health and sport drinks. The number of products purchased between the eight countries ranged from 39 to 102 (Finland = 102, France = 77, Hungary = 39, Ireland = 57, Italy = 74, Poland = 47, Portugal = 53, UK = 57).

Dairy: A total of 146 products were purchased for this food-group. This food-group focused on processed cheese products. It was divided into a number of sub-groups: cheese slices, cheese strings, spreads in tubs and spreads in metal tubs. The number of products purchased between the eight countries range from 11 to 26 (Finland = 11, France = 14, Hungary = 13, Ireland = 26, Italy = 26, Poland = 20, Portugal = 20, UK = 15).

Confectionary: A total of 414 products were purchased for this food-group. The food-group was divided into a number of sub-groups – sugar confectionary, chewing gum and chocolate confectionary. The number of products purchased between the eight countries range from 38 to 63 (Finland = 62, France = 50, Hungary = 63, Ireland = 59, Italy = 38, Poland = 43, Portugal = 42, UK = 57).

Bakery Wares: A total of 636 products were purchased for this food-group. The food-group was divided into a number of sub-groups – biscuits and cookies, wafers, sandwich biscuits, roll, sponge cakes, cakes, croissants, brioche, biscuit assortments and donuts. The number of products purchased between the eight countries range from 46 to 146 (Finland = 70, France = 91, Hungary = 77, Ireland = 78, Italy = 68, Poland = 60, Portugal = 46, UK = 146).

Meat: A total of 349 products were purchased for this food-group. Fresh meat and processed meat was investigated. The food-group was divided into a number of sub-groups – beef, pork, mutton, poultry, ham, bacon, salami, other cured meat, preserved meat. The number of products purchased between the eight countries range from 26 to 57 (Finland = 44, France = 37, Hungary = 51, Ireland = 57, Italy = 26, Poland = 40, Portugal = 40, UK = 54).

Fish: A total of 243 products were purchased for this food-group. Frozen fish and preserved fish were focused on for this group. Frozen fish was divided into unprocessed and processed. Preserved fish focused on canned fish imported from outside the EU. It was divided into a number of sub-groups – tuna, salmon, sardines, anchovies, crab and other canned fish. The number of products purchased between the eight countries range from 15 to 55 (Finland = 26, France = 25, Hungary = 17, Ireland = 47, Italy = 15, Poland = 34, Portugal = 55).
Composite Foods: A total of 223 products were purchased for this food-group. This food-group focused on chilled ready meals and was divided into a number of further sub-groups – quiche, lasagne, meat pies and sandwiches. The number of products purchased between the eight countries range from 17 to 38 (Finland = 22, France = 17, Hungary = 29, Ireland = 38, Italy = 22, Poland = 36, Portugal = 29, UK = 27).

Delivered by the chemical occurrence work-package:

- A harmonised database on targeted food chemical occurrence in 8 member states

(e) Food chemical concentration data

Obtaining accurate levels of chemical concentration data from consumed foods is a vital component in dietary exposure assessments. In the case of food additives a list exists in EU law for the maximum levels of a given food additive which can be used in a food. Maximum chemical levels, such as Maximum Permitted Levels (MPLs) may be applied to a dietary exposure assessment in the absence of actual concentration data. However, rarely are additives used at these maximum legal levels. In the case of flavourings and packaging materials, no such legal values exist and in the case of packaging, the concentration of a migrating chemical will depend on many factors, presenting a considerable challenge to the risk assessor. Obtaining data from industry in the past has been difficult because of the confidential nature of the levels of ingredients in proprietary recipes. The present study is very fortunate in having FoodDrinkEurope (formally CIAA), the EU’s largest food industry grouping as a partner who worked with their industry panels to create a sustainable database on food additive concentrations in target foods.

The present project has extended the state of the art in extending knowledge of food chemical concentration by creating a database of dossiers on all targeted food additives with concentration data for different foods and different formulations of the same food. A database on patterns of usage of different flavourings and blends of flavouring compounds has also been created. FACET has further established a migration modelling framework tool box for complex packaging materials into foods under real conditions of use in order to deliver realistic concentration estimates for consumer exposure models.

In order to guide the work on collecting additive concentration data for the FACET project, the “FACET Expert Group on Additive Concentration” was created. This was originally composed of nine industry experts. For setting up the expert group, special attention was paid in achieving a good balance between different industry sectors and countries. The expert group encompassed different types of experts (Generalist and Specialist). While the specialist experts took the lead in the discussion on food categories from their specific industrial branch, the generalist experts were able to provide general guidance on several industrial branches, and act as liaison with further industry experts when required.

(f) Food intake data

The use of relevant and appropriate food consumption data is pivotal in dietary exposure assessments. Such data reflects what individuals or groups consume in terms of solid foods, beverages and supplements. Many EU countries have programmes for the periodic collection of food consumption data and even where no national programme exists, inevitably, there are small regional surveys available or data from economic studies such as household budget surveys. The methodologies used to collect the data differ from country to country. However, even if methods were harmonised, another major variability in databases is the way the raw data is retained both in the level of detail and in the system of categorisation. Any attempt to create a “harmonised database” can only happen if the task has very specific questions to the national database managers and that is the case in the present project. Such a database will have to exist at several tiers representing different levels of definitions of food categories from highly aggregated to highly disaggregated.

The present project has extended the state of the art in extending knowledge of food intake data by developing a new tiered and harmonised food intake database structure. This database has been populated with food intake data from eight member states (Ireland, UK, France, Italy, Finland, Portugal, Poland and Hungary). In the eight participating countries, national database managers (DBM) identified a total of 19 food consumption databases, with information on subjects aged 1 month to 96 years. However, only studies with data at the level of person/day/eating occasion/food item were utilised in the FACET project, with a total of 15 surveys included in the final harmonised database.

For the re-categorisation of the databases into a harmonised system, 18 food categories were accepted and it was agreed that at the top tier all three chemical groups would use the same categories, but at subsequent tiers each group would use a separate hierarchical
system. Subsequently, 18 standardised flags were developed to assist the chemical groups with assigning concentration data. The flags are applicable to certain food categories and provide additional information on how the food was prepared, whether it was processed, the state of the product (e.g. chilled/frozen/ambient), the presence of flavourings, coatings, toppings or fillings. Due to the complexity of the recoding of the food consumption databases, a web-based interface (FWI) was developed by Fera (partner 3) and UU (partner 2), using an existing system within Fera. The FWI provides a centralised method for recoding food items into the FACET categories and application of flags.

It was determined that limited food consumption data were available in Portugal (not regionally representative, adults only, 722 food items), Poland (1 day records with 644 food items) and Hungary (adults only, 537 food items). There were also limited data available for children under 5 years (less than 4% of FACET total), younger adults (18-25 years less than 5.5% of FACET total) and older adults over 65 years. Data gaps, relative to FACET age groupings, within countries were also evident with only Italy and Poland covering all age ranges. Finland, Hungary and Portugal were only able to provide food consumption data on adults. The food consumption databases used in the FACET project were not originally designed to estimate exposure to Additives, Flavourings and Packaging materials but rather nutritional intake. Therefore data gaps exist at varying levels of the hierarchical food classification system used. In order to populate these gaps with data from the eight EU countries participating in FACET, it was decided to pilot the usefulness of a targeted food frequency questionnaire (FFQ), specific for the data gaps in the food consumption databases of the FACET partners. A different approach for populating data gaps from the questionnaire was required for Additives, Flavourings and Packaging.

Different data gaps were identified for each of the 3 chemical areas and suitable questions were drafted to cover each area:

1. Additives - foods containing artificial sweeteners or labelled with "no added sugar"
2. Flavourings – use of selected herbs and spices when cooking at home
3. Packaging – typical type of packaging for takeaway foods

Seven countries took part in administering the FFQ. The questionnaires were administered electronically (see http://www.surveymonkey.com online) utilising drop down lists for answers. National DBM were responsible for deciding the method of obtaining responses from a minimum of 500 adults in the age range 18-94 years (due to ethical considerations in the UK this was revised to 70yrs). A total of 4710 participants completed the survey across 7 countries. Similar to the national food consumption surveys, the food items targeted in the survey for Additives and Flavourings were generally reported as not being frequently consumed. Therefore these may be considered as "true" data gaps or it could be due to a number of factors including subjects being confused/not aware of foods that contain artificial sweeteners/herbs or spices; lack of awareness of products containing artificial sweeteners; subjects not cooking composite dishes at home using basic ingredients but instead using "ready-made" items such as prepared sauces.

(g) Regional Modelling
The risk management of chemicals in food requires knowledge about the amounts of food containing those chemicals that are consumed. Certain individuals habitually consume more of certain kinds of foods than others and these people must be taken into account in the risk equation. Age is particularly important because children have considerably higher energy requirements and thus food consumption than adults on a body weight basis. Children may also have different tastes in food, often preferring sweetened, brightly coloured or attractively flavoured foods. Diet is frequently related to culture, which is in turn related to geographical location, which determines the availability of certain types of food. There are therefore regional differences between diets that must be taken into consideration. As a consequence it is critically important to include high consumption, special groups of consumers, and different age groups on any risk management strategy.

For many reasons it is virtually impossible to achieve a complete set of contemporary, comprehensive and representative dietary intake data for all population groups residing in the European Union. Furthermore, dietary intake surveys age quickly given the dynamics of the food industry (global suppliers, restaurants, processed food products, ingredient substitutes, etc.). FACET is dealing with this challenge by developing a mechanism for gathering the considerable amounts of contemporary information that are available. Considerable amounts of health-based, epidemiological, commercial and economic data are produced in most countries at the national level. This information, together with per capita national consumption data, can be used to extrapolate from detailed information about food consumption in neighbouring countries to produce surrogate models to represent populations where data are presently absent.

The present project has extended the state of the art in the development of regional models. A novel modeling approach to generate surrogate data to represent missing national dietary patterns was developed. Bayesian analysis and formal elicitation of expert opinion was used to refine intake models and these underwent thorough internal validation. Because different food consumption surveys contain different levels of detail it has been necessary to develop a hierarchical approach, described under the food intake work-
package section. For regional modelling, it was necessary to identify a suitable level in the hierarchical approach to extrapolate food consumption patterns to populations or population sub-groups that presently have no consumption data. The grouping level allows for a sufficiently detailed approach whilst considering the practical limitations of including large numbers of highly specified foods. Grouping at a high level of aggregation would result in data of limited value, so a technique was developed to allow grouping at the highest level of detail.

An objective method for identifying donor-recipient partners was required so the application of cluster analysis techniques of country consumption patterns in Europe using the DAFNE and EFSA data was investigated. Three main clusters were identified but the clustering was not very strong and there was much overlap between groups. The overall conclusion was that the variance within countries probably out-weighed variation between countries so that the concept of clustering based on national boundaries became irrelevant. This was important because it meant that ‘donor’ data could be combined from several countries to provide a more solid statistical basis for the re-sampling process. It was observed that the existence of clusters was driven by certain high-volume foods such as beverages (tea, coffee, fruit juices). When the same metric was used but after standardisation for weight consumed, the clusters disappeared.

FERA (partner 3) focussed on the development of techniques and algorithms to underpin the European model for extrapolation of national food consumption patterns. This led to investigations into existing data sources and food consumption modelling techniques and to the development of novel statistical methods. Four main ways of modelling a country’s dietary records were investigated: resampling from existing dietary records, stochastic process modelling, hierarchical probabilistic modelling and a combination of hierarchical modelling and resampling. To test these modelling techniques, two countries (Ireland and UK) were used to extrapolate consumption in a third country (Italy). Modelling based on a full Bayesian approach and on the Bayes Linear approach was considered. It was decided within FACET that single day diaries are unsuitable for chronic exposure assessment and so these were not used as the basis for extrapolation. It was agreed that all surrogate data would be based on a three-day average. Survey data based on 4- or 7-day surveys (i.e. UK data) would need to be sampled to obtain consecutive 3-day data.

The approach developed was then applied to other test case countries in FACET and estimates for identified food groupings, sub-divided by appropriate age bands were produced. Specific foods were selected from the food groups that are marketed in uniform product sizes (e.g. certain soft drinks), so that food frequency data could provide a reasonable estimate of consumption. It was agreed that food consumption data gathered in the food intake work-package and more on internal validation. It was felt that it would be difficult to make direct comparisons between FFQ data and food consumption data obtained from diaries. Internal validation relied on the use of the extrapolation modelling tool for developing food consumption databases for countries and age-groups that already had complete data sets.

(h) Modeling exposure assessment

Deterministic exposure assessments are straightforward spreadsheet calculations that do not take into account the demographic diversity, variability or uncertainty of an exposure assessment. The result is intended to be a conservative point value estimate which is thought to be well above any realistic range of exposure, but does not provide any estimate of how likely the exposure would be to occur. Simplistic probabilistic exposure assessments can be performed by products like @Risk or Crystal Ball where probability distributions are used to quantify uncertainty and variability in the inputs and outputs of exposure assessment. Specific food safety exposure assessment models have been developed which allow more detailed probabilistic models to be used, these models include the CREMe 2.0 model, the MCRA model (RIKILT) and the CSL model. These tools have allowed uncertainty and variability to be quantified in more detailed exposure assessments. In practice, many current exposure assessments follow standard screening procedures that are intended to produce conservative estimates of exposure. These screening assessments do not involve an analysis of uncertainty, provided that they include conservative assumptions. The requirement for increased transparency in risk assessment in food has been articulated in recent publications by the European Commission. Furthermore, it is necessary to characterise scientific uncertainty so that risk managers can determine when to take appropriate measures and where best to target their resources to gather the information required.

The present project has extended the state of the art in the development of food chemical exposure models. Validated software for deterministic and probabilistic modeling of food chemical intake has been developed and is now available for public use. FACET has quantified variability and uncertainty in the probabilistic modeling of food chemical intake and the models have been propagated with confidence intervals for estimated intakes. All databases have been successfully formatted, harmonised and integrated into the various dietary exposure models developed over the course of the project. The various models developed have been tested and their implementation validated. A detailed inventory was made of uncertainties affecting the model, and additional software was developed
to assist users in evaluating the impact of uncertainties on exposure assessments produced with the FACET models.

The bulk of the work was the continuous development and refinement of the exposure models appropriate for this assessment tool. In order to develop and implement the models, this work-package had an extensive liaison with all the data collectors and providers in the project concerning the data requirements for the models. The structure, format, and content of all data was investigated in detail with all partners both before, during, and after the collection process, to ensure that the exposure models could adequately provide for the data and vice versa. A software specification for the FACET exposure tool was developed during this period to guide the development of the software to meet the needs of all partners. This was led by Partner 4 (CEPE/FIG). Several draft software tools were delivered during the course of the project, which included a mature user interface and implementations of the exposure models for flavourings, additives, and food contact materials.

Potential impact
At the outset of the FACET project, there were many limitations with respect to conducting exposure assessments to food chemicals in Europe (for a more detailed discussion on this refer to section 4.1.2). Therefore the FACET was funded in an attempt to solve these limitations by creating a surveillance system sustainable beyond the project. This momentous task has been achieved with the delivery of the final FACET software.

The impact of the availability and use of the FACET software for conducting exposure assessments to food additives, flavours and food contact materials will be evident at a number of levels:
- Protection of the consumer: Consumers need to be assured that the risk assessor and risk managers have pushed to the limits of knowledge all aspects of protection from chemical hazards in the food supply. The FACET software will provide such re-assurance in a wholly transparent way, with full regard to national and regional differences, the young, the elderly and any other group that may be exposed above the average.
- Fostering innovation: Innovation in the food chain, at all levels, is essential in developing to the highest level a safe and nutrition food supply. Lack of information requires conservative assumptions and this can inhibit innovation. A fact-based science-driven, transparent risk assessment approach in respect of exposure assessment will meet the dual needs of the consumer and the food innovator.
- Driving the scientific approach: The EU espouses the concept of the precautionary principle in the protection of consumer health and welfare and this is seen as an approach necessitated by a lack of adequate supporting scientific data. By providing the missing data along with an understanding and tools on how to use it, uncertainty is reduced and consumer confidence is increased.
- Influencing international food regulatory affairs: The EU along with all other nations plays a role in global food regulatory affairs through Codex Alimentarius or the FAO/WHO Joint Expert Committee on Food Additives. The EU will, at the conclusion of FACET, have a strong scientific base to underpin their contribution to such regulatory issues.
- Focused risk management: If an unexpected chemical is detected in food, enormous resource and effort is directed towards further investigations, frequently resulting in many member states undertaking surveillance surveys at high cost. If a risk management tool existed to put the meaning of this ‘discovery’ into context, such as the FACET software, then use of exposure estimates would enable authorities to focus effort proportionate to the exposure/risk.
- Thresholds: Most chemicals have what can be considered to be toxic thresholds, below which there is no cause for concern. The FACET project is the first European-wide project to enable estimates of exposure to chemicals in food to be derived and use to inform Risk Management options. Depending on the level of exposure, animal testing which today is mandatory may be reduced.
- QSAR: This is in its infancy for migrants from packaging, although well established for pharmaceuticals. It is necessary to predict the toxicity of a chemical in order to assess its risk. Traditionally animals have been used for toxicity testing. The use of QSAR will enable the toxicity of a substance to be predicted and thereby reduce and replace animal testing.

Dissemination activities
A specific work-package in FACET was established to take responsibility for managing the dissemination activities throughout the project. The overall goal of these activities was to communicate the aims and objectives of the project to a wide audience and to disseminate the results and findings from the project, both during and on completion of the project and also to disseminate the development results from the software models developed in WP8.

During the first period of the project, a unique logo and a website for the project were established. The FACET logo was used on all printed and web-based material associated with FACET. It was also used on all presentations and posters where details of the project were disseminated. The web address for the project is: [http://www.ucd.ie/facet](http://www.ucd.ie/facet). The project website contains all information related to the project both for the general public and for project partners. Internal pages contain information on meetings, internal reports and project coordination activities. Internal pages are password protected, and these passwords were changed at regular intervals within the
duration of the project to maintain security.

Exploitation of results
In relation to exploitation of results in the FACET project, especially with regard to the final software tool at the end of the project, training materials have been developed for the use of the models and software tools by Creme. JRC as part of Commission will contribute to the dissemination and exploitation of results of the project by organising the final workshop. The final workshop is to be held on the 26th October 2012 in Brussels, and invitees include, aside from project partners, members from the additives, flavours and food packaging industries and experts in these areas along with experts in food intake and food chemical exposure assessments. Members from governmental bodies such as food safety agencies and risk assessment agencies are also invited. Project partners are fully encouraged to publish their research findings from the FACET project in peer-reviewed journals, and several papers were published during the course of the project.

Sustainability
The concept behind the FACET project is the creation of a food chemical exposure surveillance system, sustainable beyond the life of the project, which meets the needs of the EU regulatory authorities in the protection of consumer health. The FACET tool (software and the databases) will be freely available at the end of the project. It is intended that the surveillance system developed in FACET will be capable of being both sustained and developed for use by EU regulatory authorities. However, after the 31st August 2012 the project funding under Seventh Framework Programme (FP7) ceases and the contractual agreements established between the project partners provide only an outline framework for maintaining the tool (databases and software). In order for this tool and the underlying approach to dietary exposure assessment to be adopted by the European Commission, the software has to continue to be useful and usable beyond the end of the FACET project. In order to ensure continuity after the finish of the project, a group from within the FACET consortium has formed to maintain sustainability of the FACET software, so called the ‘FACET User Committee’. This committee will represent the interests of additives, flavours and food packaging materials.

A report was compiled with four main objectives:
1. Establishing how best to manage distributing the FACET software and
2. Transferring source code to the JRC in case project partners are unable to maintain the tool
3. Transferred publicly available data to the JRC databases
4. Transferring the exposure models to the JRC databases

List of Websites:

http://www.ucd.ie/facet

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