PROJECT FINAL REPORT

Grant Agreement number: 211686

Project acronym: FACET

Project title: Flavours, additives and food contact material exposure task

Funding Scheme: Large Collaborative Project

Period covered: from 1st September 2008 to 31st August 2012

Name of the scientific representative of the project's co-ordinator[1]:

Professor Mike Gibney, University College Dublin, Ireland

Tel: 00 353 1 716 2824

Fax: 00 353 1 716 1147

E-mail: mike.gibney@ucd.ie

Project website address: www.ucd.ie/facet

[1] Usually the contact person of the coordinator as specified in Art. 8.1. of the Grant Agreement.

TABLE OF CONTENTS

4.1 Final publishable summary report

4.1.1 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.

4.1.2 Summary description of 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. Exposure is defined as the amount of the substance per mass of consumer body weight per day (Holmes et al. 2005) and may be expressed as:

Exposure	**=**	**Chemical Concentration**	**x**	**Food Consumption**
(mg/person/day)		**(mg/kg food)**		**(kg food/person/day)**

At the outset of the FACET project, the *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.

More specific details relating to the objectives for the main research areas of the project are now presented.

(a) 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

4.1.3 S&T results / foregrounds

(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.

In parallel, a database was created linking food categories and additives authorisations, with the 470 food categories used in the additives classification. This additive database that has been developed at the end of the codification work has been designed to link the MPL (maximum permitted level) of all authorized food additives with the codified food categories. This database was initially developed on the basis of the former additive directives (Dir 94/36/CE for colours, 94/35/CE for sweeteners and 95/2/CE miscellaneous additives), and adaptation to the new regulation has been necessary (Reg 1333/2008). This adaption was only completed during the 3rd period of the project as the annex II of the regulation was published in November 2011 (this annex gives the details of the MPL by food category). Although no major changes were made in this annex, the food classification system had changed (the authorisations are now presented by food category and not by additive as in the previous Directives) and some MPL's had been modified (some new authorizations arose and some MPL's had been decreased following EFSA re-evaluations and the

corresponding Commission risk management measures). An update of the database was then necessary to reflect these changes along with a complete verification of the database. This database will enable the software to calculate a tier 2 exposure assessment (real consumption data combined with MPL) for all food additives (except those used quantum satis).

Prior to their codification in the additive codification system, the dietary surveys from the 8 participating countries (UK, Ireland, Italy, France, Portugal, Poland, Finland and Hungary) have been evaluated in order to determine if they provide enough detail to allow the correct codification of food for additives. The characteristics of all the dietary surveys have been gathered and a report on this evaluation has been written. Except from FFQ from Portugal, all dietary surveys available are adapted to additive exposure assessment. A list of 32 high priority additives was decided upon for target in the project for more realistic exposure assessment, as it was not possible to gather occurrence and concentration data for all authorized additives. 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* (qs) or with maximum levels, and certain target additives selected or who had their ADI recently modified by EFSA. These 32 additives will be assessed at the higher level of accuracy by the software, when remaining additives will be assessed at a rougher level, depending on available data. For the additives or food categories not covered by the work-package on occurrences, a complementary search has been realized, in order to have occurrence data for the 31 priority additives in all food categories. For that purpose, data have been gathered from a marketing database and the occurrence of additive calculated for the 8 participating countries (UK, Ireland, Italy, France, Portugal, Poland, Finland and Hungary).

Parameters of deterministic and probabilistic approaches in relation to additive exposure assessments have been identified and discussed. The consumer loyalty to some brands has been taken into account, as consumers of a single brand may be more exposed than the general population to an additive (when this additive is more frequently used or at a higher level in the consumed brand than in other available brands). An extensive bibliographical work has also been completed on the subject and calculations have been realized in order to simulate usual intake from short term dietary surveys.

Delivered by the Additives Work-Package:

- A report on the list of dietary surveys suitable for exposure assessment for food additives
- Procedures to codify foods according to EU food additives directives including the new regulation and GSFA and the codification of dietary surveys according to these procedures
- A list of high priority food additives for the collection of use levels

- A report on exposure assessment methodology for food additives, including original results

(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 (Flavis No.; Flavis 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.

A total of 41 flavouring substances (38 flavouring substances, 2 solvents/carriers, 1 non-flavouring substance present in flavouring preparation) were selected in order to represent a large variety of flavouring substances and illustrate major methodological problems that may occur in the assessment of exposure. They also represent a variety of cases in terms of potential toxicity and of availability of safety limits. A database of reported concentration levels of the target flavourings in foods was developed. The database is organized according to food descriptors that are compatible with the food descriptors of food consumption data. The database was filled by making use of all available sources of reported concentration levels of flavourings in food. Differently from what was foreseen in the technical annex of the project, it was considered important to gather data not only on added use levels but also on the natural occurrence. This will allow the estimation of dietary

exposure not only due to the addition of the flavouring substances, but also from their natural occurrence. Information on concentration levels due to the natural presence of the target substances in foods were gathered in a separate database with a different structure. Data on natural occurrence were retrieved from the TNO database "Volatile Compounds in Foods" (version VCF12.3). Data was available for 32 among the 41 target flavourings, and quantitative data was available on 31 substances.

All available information regarding food product identification and concentration levels or simple qualitative information about natural presence was reported in the database. These data were organized according to the FACET food categorization system and were inserted at the most disaggregated level of food categorization. Whenever possible also the food descriptors system developed as "flags" were used to provide a more refined identification of a food product.

To allow the dietary exposure to flavourings, a categorization system for food products was developed for working with the food consumption surveys in the eight EU member states. For each food item consumed in the consumption surveys, the categorization system would allow assumptions to be made on the presence of:

- Flavouring substances added to homemade and industrial processed food
- Flavourings naturally present in some foods (banana, raspberry, etc.)
- Flavouring substances present in spices and herbs (coumarin, safrole, etc.) added in the preparation of food and/or present in the list of ingredients in industrial processed foods.

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 flavourings 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 that 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, γ-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-shops. In the second part of the study, transfer rates for linalool and linalyl acetate from tea leaves into the tea beverage in the course of the hot-water infusion were determined.

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: α-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, γ-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.

Pineapple flavoured foods/beverages: In order to assess the variability of concentration levels of allyl hexanoate in two main food categories to which it is often added, pineapple juice-based

beverages and yogurts containing pineapple, analytical determinations were performed on a number of commercial products belonging to these categories and purchased from the Italian market. Samples from 34 beverage products, all based on fruit juice and containing variable amounts of pineapple juice and added flavourings, and samples from 29 yogurt products, all reporting pineapple fruit and flavourings in the ingredient list, were collected and analysed. For this purpose two distinct analytical methods based on the Stir Bar Sorptive Extraction (SBSE) technique for the isolation of the target analyte, and on GC-MS analysis for final determination, were developed for the two food categories. Analysed products were divided in two groups: the first in which pineapple represents the only or the main fruit ingredient and the second formed by multi-fruit beverages, in which pineapple is one among many fruit ingredients. In the first group, allyl hexanoate ranged from <0.01 to 16.71 mgL^{-1} (average level of 1.91 mgL^{-1}). In the second group where pineapple fruit is a minor fruit ingredient, allyl hexanoate was generally present at low level, in 5 cases out of 11 being lower than 0.01 mgL^{-1}; the average level was 0.23 mgL^{-1} and the maximum was 2.28 mgL^{-1}. In yogurts from whole-fat-milk with pineapple as the only or the main fruit ingredient, the average level of allyl hexanoate was 13.17 $mgkg^{-1}$, (range 0.84 - 89.41 $mgkg^{-1}$). Exposure in Italian children who are high consumers of pineapple yogurt or beverage products containing the highest observed level of allyl hexanoate could exceed by up to 2.4 and 1.3 times, respectively, the ADI established for this substance.

Cola Drinks: The variability of concentration levels of *tr*-cinnamaldehyde, safrole and myristicin in cola-flavoured soft drinks was assessed in order to gather information about the variability of levels of flavouring substances present in food or beverages, mainly as added natural flavourings. Samples of cola soft drinks were purchased from local sales point in 7 countries (France, Hungary, Ireland, Italy, Poland, Portugal, UK and Sweden). The types of cola beverage considered were the normal cola formulation (original version), 54 samples, and a limited number of other types of cola, such as the diet versions, 9 samples. A total of 63 cola soft-drinks samples were collected: 29 from two major brand leaders and 34 from private brands. Products with different typologies of packaging were purchased, some in cans, other in small or large plastic bottles. An analytical method based on the Stir Bar Sorptive Technique (SBSE) for analyte isolation and GC-MS for final determination was developed. The level of the three substances considered is fairly constant in samples of brand leader products purchased approximately at the same time (within a period of 2 months) in 8 European countries. The diet versions of these products contained level of these substances that were similar to those found in the normal versions. A higher level of variation was observed, as expected, in the group of private brands products, representing a more heterogeneous collection of commercial products, with differing formulations.

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 SPET.

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) <u>Packaging material migratory substances</u>

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.

Expertise on packaging materials and their use and composition rested largely with industry in the FACET project. For packaging composition and usage, most of the information came from the Packaging Trade Associations that were in the project and were represented by the FIG - The FACET Industry Group. FIG covers three sectors, namely plastics, metal, paper and board. The three sectors are further subdivided into flexible and rigid plastics, rigid and semi-flexible metal, paper and board. The different industry sector groups - plastics, metal coatings, paper and board, inks and adhesives submitted lists of substances used to make their materials for the project. The FACET inventory list contains almost 7,000 substances that are either single substances or are defined or non-defined mixtures of two or more substances.

Categorisation of the food consumption databases was conducted in order to link foodstuffs with the different materials that they could be packaged in, including quantitative information on market share, food weight, contact area ratios and storage conditions. This was done in close conjunction with the Additives and Flavourings Work-packages along with WP5. At the highest level there are 18 food categories. Thereafter, the lower tiers diverge for packaging, additives and flavourings because of their different requirements and legal (authorisation) basis. The lower tiers reflect packaging of the foodstuffs, which ties in with packaging usage data obtained from market surveys.

As part of the Matrix project the plastics supply chain consortium commissioned a market research organisation – EuroMonitor (EM) – to provide data to identify the market shares of different types of packaging for the same foodstuff. These data record the split between different pack sizes, enabling an improved estimate of surface to volume ratios. The consortium then defined different types of packaging materials which could be used for the different types of foodstuffs. The FIG purchased from EM packaging usage data for 19 EU Member States for packaged foodstuffs and 20 EU Member States for unpackaged foodstuffs. With the involvement of the FIG, there are 247 packaging material descriptions. The types of packaging material for each foodstuff have been connected to the probability of different substances being present in that material. The need to collate food packaging usage necessitated the development of LINK and PASTA tables to facilitate the process. Commercial research by EM gave figures for quantities, types and retail sizes of packaging used for different foodstuffs. The raw EM data was converted into a working spreadsheet called the “LINK” table. This was used to manipulate the data further into what was needed for FACET. The PASTA (PAck Size, Type and Association) table is essentially an extract from the LINK table. The EM codes for food and pack component type were “translated” into FACET codes using agreed “dictionaries”. Lastly, the producers of the materials provided information on the occurrence (based on European market statistics) and the concentration distributions of the different substances used to make the 247 material types. On completion of FACET this has produced the link between the FACET packaging chemical substances, the packaging material types, and the Food categories.

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) $K_{P/F}$). 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 and PA) selected, three representative paper/board samples were provided by the paper industry for study.

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.

Delivered by the Food Contact Material Work-package:

- List of substances used in packaging materials for foodstuffs and a list of foodstuffs which are packaged in those materials
- Report on testing the database for estimating exposure to a number of test substances
- Migration model to calculate concentration data in foodstuffs, with verification for selected substances for use in exposure model
- Probabilistic migration model into foodstuffs, with experimental verification, for multi-layer/multi-material FCMs
- Report on verification of QSAR approach for migrants from food packaging materials.

(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 flavouring substances 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 >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.

As certain partners within the project required specific food-groups to be collected in order for detailed occurrence data to be gathered on, they provided particular categorisations to be purchased within the food-groups. The “packaging” work-package selected canned fruit & vegetables, sauces, meat and fish (specifically targeting canned and jarred products imported from outside the EU), and takeaway foods. The “flavouring” work-package selected baby foods, non-alcoholic beverages and dairy foods. The “additives” work-package selected desserts, confectionery and bakery wares. In order to select which branded product from each food category were to be purchased and entered into the database for the occurrence survey, market share data was purchased from Food For Thought (FFT) (www.fft.com) for all eight countries. However, as FFT did not produce data on supermarket or hard discount stores own labels, research was conducted on the most popular stores in the eight partner countries. The top four supermarket and top four hard-discount stores were selected. Own label ranges from the first supermarket and first hard-discount

store on the list were to be the first searched for targeted products. If the targeted product could not be found in the first supermarket/hard discount store, the second supermarket/hard discount store was searched, and so on until the targeted product was found. A total of 3,778 products were purchased between the eight countries involved.

Along with entering detailed information (including ingredient, nutrient and packaging data) about each product into the MS Access database, the packaging was photographed. The components of the packaging were then individually coded, packaged and sent for further analyses to Innventia in Stockholm, Sweden. This protocol was followed for all products purchased for each food-group by all eight countries. At the end of data collection and data entry all Access databases were sent to UCD (partner 1). Quality control was then conducted on all databases. For populating the occurrence database with data gathered from the packaging of the food products, members from FIG organised a training day for the national database managers on identifying different types of food packaging. A sample of the packaging was also taken and shipped to Partner 12 (Innventia) for further analysis and verification. In the case of rigid metal packaging, the filled cans or the closures from jars were sent to a member of FIG (EMPAC) for identification of the coatings. For the samples sent to Innventia, there was identification of the food contact layer for more than 5000 samples (many packs had two or more components) by FT-IR and in many cases through pyrolysis GC-MS or x-ray. In total, more than 7500 different measurements and investigations were completed by Innventia.

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 brulee, “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 & 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 = 24, UK = 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.

Based on the list of 32 priority additives established by the additives work-package, industry questionnaires for providing additives usage levels were developed. The questionnaires consisted of different tables in which the typical and extreme concentration values or ranges were completed by the data providers for each additive and each food category in which they are permitted according to the current legislation. The reporting questionnaires were distributed among FoodDrinkEurope's membership, which is composed of 26 national federations, including 3 observers, 26 European sector associations and 19 major food and drink companies (also the national federations and EU sector associations have additional members to whom the request for data was forwarded). The compiled information collected by FoodDrinkEurope was sense checked by the "FACET Expert Group on additive concentration" and representative values have been characterized in order to allow the software to generate a distribution of concentrations for each targeted additive.

In order to provide as accurate exposure estimations as possible, it was important that in the database on additive concentration, special attention was paid to the types and sources of uncertainties. FERA (partner 3) developed an uncertainty table tool, to deal with uncertainties in different sources of data to be used in the software.

Delivered by the Additive concentration work-package:

- Database on the technological use and ranges of food additives selected for study within the FACET project

(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 (<4% of FACET total), younger adults (18-25years <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 (via www.surveymonkey.com) 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. The FACET targeted FFQ was a useful tool for the purposes of Food Contact Materials with specific reference to takeaway foods with subtle between country differences in pack type and frequency of consumption. The majority of participants in the UK and Ireland consumed Chinese or Indian food "less than once per month" in foil and/or plastic dishes, whilst the majority of participants from the other countries reported never consuming them.

Delivered by the food intake work-package:

- A harmonised database on nationally available food intake data from eight EU member states to represent the range of EU regions. These are Ireland, UK, France, Italy, Finland, Portugal, Poland and Hungary.
- Guidelines for the appropriate use of the harmonized database
- A report on the value of targeted ancillary food frequency questionnaires for the estimation of food chemical intake

(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 to place less emphasis on the use of FFQ 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. For this it was decided to limit activities to one initial extrapolation covering children aged 3 – 9 only and using France as the donor country, followed by a limited set of extrapolations designed to demonstrate the capabilities of the software. The initial assessment was then used to extrapolate into the UK where data for children aged 3-9 were available for comparison which would then enable some model validation to be undertaken. Three scenarios were examined:

1. Extrapolation 1: An extrapolated database for the UK, based on donor dietary record data from France (FR to UK).
2. Extrapolation 2: An extrapolated database for France, based on donor dietary record data from the UK (UK to FR).
3. Extrapolation 3: An extrapolated database for Ireland, based on donor dietary record data from both France and the UK (FR,UK to IE).

Each database contains a 3-day food consumption record for 2000 simulated individuals in the age range 3-9, and is structured at a highest level of the FACET food code classification. For each case

study it was recognised that the extrapolated database was only the initial extrapolation from the FACET WP7 extrapolation model, and not a finalised database for the recipient country. The next stage of the modelling framework would involve a series of expert elicitation exercises with the appropriate database managers and dietary experts, where at each stage the database would be further refined.

Delivered by the Regional Modelling work-package:

- European model for extrapolation of national food consumption patterns
- Database of national food consumption
- WP7 Validation report on the database of national food consumption

(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 has 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.

In addition, considerable effort was put into understanding and describing the variability and uncertainties in the data being collected by all project partners, which have also been accounted for in the model. When and wherever possible, the variability surrounding all data gathered in the FACET project was described quantitatively. However, many of the uncertainties affecting exposure assessments are not quantified by FACET due to the volume of data gathered over the course of the project and the work required to quantify the uncertainty associated with each data set. Nonetheless, uncertainties have to be accounted for using an appropriate method. This has been achieved using the concept of uncertainty tables, which was introduced by EFSA's 2006 Guidance on uncertainties in dietary exposure assessment and comprised the following key steps: systematically examine every part of the assessment for potential sources of uncertainty; list the identified uncertainties in a table; evaluate by expert judgement the impact of each uncertainty on the outcome of the exposure assessment, using a suitable scale; and evaluate the combined impact of all the uncertainties, considered together, on the outcome of the exposure assessment. A software tool was developed to help users conduct their own uncertainty evaluations, and will be available for downloading together with the FACET exposure model software. The calculated assessment involves simplifying assumptions, so it should not be taken as a definitive result but used as a starting point to assist the user in forming a considered judgement of the overall uncertainty. Further explanation and guidance is provided in help pages via links in the software tool.

An online, centrally customised data management system was implemented early in the project. The most efficient procedure for loading data to this system was for partners to email data directly to

partner 15 (Creme software), who then formatted and loaded the data onto the system as required. This system was used by the food consumption database managers as an aid in the effort to recode the consumption data using the agreed FACET food categories. All releases of the software and models have been tested extensively by project partners.

Partner 18 (INCDTIM) and Partner 9 (FABES) developed a model of migration of substances from packaging into foods. As part of this work, Partner 18 developed a software module that implements a simple 1-D migration model based on Fick's Second Law of Diffusion. This runs as a separate program within the FACET software and has been successfully integrated, along with all data inputs for calculating the necessary physiochemical parameters. The module has been successfully applied to all combinations of data provided by industry, using the FACET coding system applied to packaging materials and foods. The output of the module (i.e. the concentration of migrants in foods) has been successfully integrated into a broader dietary exposure model.

All versions of the software are available from Partner 15's website at: www.cremesoftware.com/facet with username and password for access available from Partner 15 on request. The final version of the software will be available for download on the JRC's website, who will manage the distribution of the software beyond the project period.

Delivered by the Modelling Work-package:

- Draft exposure assessment software tool for external evaluation. Final exposure assessment software tool, PC based and publicly available
- Model Validation Report
- Exposure analysis report
- Software manual
- Software technical documentation

4.1.4 The potential impact, dissemination activities and exploitation of results

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.

Above that, FACET will improve additives exposure assessment by developing a methodology for additives usually not studied (additives authorized *quantum satis*): identification of concerned food categories using marketing database, targeting food industry for the data collection etc. FACET will above all constitute a perfect tool for post market monitoring since it reflects the real exposure of a targeted population to a food additive, taking into account the variability of concentration and the real occurrence of the additive for each food category where it can be used.

Until now the only tools available to assess dietary exposure to flavouring substances were screening techniques. Thanks to the FACET project it will be possible to assess the uncertainty in these screening techniques, to identify which percentile of the dietary exposure in the population these techniques assess and, when needed to perform refined exposure assessment of specific flavourings in different population groups. The software will be useful both for risk assessor and risk managers. It will probably stimulate the provision of refined use level and of data on probability of addition by the flavour industry, so that refined exposure assessment can be performed.

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: 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. The FACET website provided a valuable tool for the entire consortium, to keep in touch with the progress of the project, and also to obtain information about the project as a whole (e.g. minutes of meetings). A flyer was also developed in the initial stage of the project (electronic format). Along with being distributed to all FACET partners, the flyer is available for download from the FACET website. The flyer contains general information about the project and about the consortium, the aims and objectives of the project and its potential impact in the area of exposure assessment. It also provides contact details for the project coordinator and project manager.

Members of the FACET consortium actively disseminated the FACET project throughout the four years. This included oral and poster presentations at conferences and workshops and publication of papers in peer-reviewed journals. Also there were many presentations of the FACET project to different industry groups, such as to members of the additives, flavours and packaging industries.

Internally, the entire consortium met up once a year at the General Assembly meetings organized by partner 1 UCD. At these meetings, work-package leaders updated the consortium on the ongoing and future research and work being conducted, and the project coordinator and manager updated the consortium on any management issues. The Facet Executive Board (EB) chaired by the coordinator, is composed of the work-package leaders, the chair of the Facet Packaging Industry group (FIG) and the project manager. The EB met at least twice a year. The EB meetings provided the coordinator an opportunity to relay information to the WP leaders about updates from the Commission, issues with any partners or work-package, reporting guidelines and any other issues relevant to FACET. The Facet EB was supported by the external consultative group. The external project consultative group (PCG) consist of 5 experts external to FACET established during the first 6 months of the project.

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.

It is essential that the EFSA, Authorities & Regulators, Commission, Food industry & packaging industry, accept FACET as the tool for risk assessment / management. Member State, Commission and EFSA meetings are planned for the coming months, even after the FP7 funding ends such is the commitment of the partners. EFSA enquired in June 2012 if FACET could be used to estimate human exposure to BPA as part of their public request for exposure data for BPA. The exposure to BPA originating from the use of epoxy resins in can coatings will be estimated using FACET.

In order to ensure that the FACET software tool is sustainable beyond the duration of the actual project and that the results from FACET are fully exploited, a specific committee to drive this was established during the final period of the project, and is discussed in the next section.

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 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. An interim chair Dr M. Knowles (FDE, and chair of the European Technology Platform 'Food for Life') has been appointed. The constitution and governance of the group still needs finalising, but it will be a combination of institutes and industry. Funding for the User Committee will be sought from industry, the EU Commission, JRC and EFSA. A guidance document has been drafted to help direct this committee to ensure that the sustainability of the FACET software tool is achieved. The JRC is actively involved in the sustainability and Crème have met with the JRC to discuss transfer arrangements. Copies of all documents, databases etc that are the output of FACET are stored by Crème and shared with the JRC.

In order to ensure continuity after the end of the project, those partners (Fera, Creme, FABES) supplying the software have agreed to continue to modify it. If for any reason they no longer wish to do this then the source code will be assigned to JRC. These arrangements are echoed and expanded upon in the FACET Consortium Agreement. The software tool and data will continue to be made available on completion of the project. The software source or object code will not be available. For the following 6 months after the release of the final version of the software any faults in the functioning of the software delivered at the end of the project will be fixed free of charge. If any development work is required to the software in future for required changes, updates or bugs FABES, FERA, INCDTIM and CREMe will be available to implement those changes. If, for any reason these organisations are unable or unwilling to support the continued updating of their part of

the software code then that organisation will within a reasonable time release sufficient rights in the software code intellectual property developed during FACET to the JRC to enable JRC or third parties in collaboration with JRC to undertake the necessary work. This includes the situation where any of the organisations are closed down or cease to trade. If rights are granted to JRC they will be limited to those required for modifications and/or updating requested by the industry partners of FACET and within the scope of the FACET project (i.e. for application to flavours, additives and packaging materials), and will not include use or modification for any other purpose.

An organizational framework beyond the current project is required for sustaining the model and associated software. A guidance document has been prepared which outlines the issues that will need to be considered in developing a framework to maintain the FACET tool. Ongoing support required by a software program can be divided into three general areas:

- Correction of bugs identified by users;
- Updating of the program and databases that reflect temporal changes in society (changes in diets, food composition, composition of plastics, and materials and sizes of food packaging.)
- Incorporation of new functionalities in the software in response to user requests

The project has the EU's own Joint Research Centre (JRC) as a partner. The JRC has a strong institutional mission in exposure assessment and it is agreed that they will sustain the legacy of the FACET project beyond its completion. The software tool and databases will be hosted on the JRC website after the project concludes in order for the software to be disseminated appropriately. Based on JRC's past experience with similar tools, users will register to download the tool with their email address and affiliation, and a database will be generated in order to notify users of updates to data, software, and models. The JRC performed a review of its existing exposure assessment tools in order to see how best to sustain the FACET software. 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

.

4.1.5 Contact details

Prof. Mike Gibney
Institute of Food & Health
University College Dublin
Room 2.05, Science Centre South
Belfield Dublin 4, Ireland
Phone : + 353 1 716 2824
Fax: + 353 1 716 1147
Email: mike.gibney@ucd.ie

Project website: www.ucd.ie/facet

4.2 Section A (public)

TEMPLATE A1: LIST OF SCIENTIFIC (PEER REVIEWED) PUBLICATIONS, STARTING WITH THE MOST IMPORTANT ONES										
NO.	Title	Main author	Title of the periodical or the series	Number, date or frequency	Publisher	Place of publication	Year of publication	Relevant pages	Permanent identifiers[2] (if available)	Is/Will open access[3] provided to this publication?
1	Exposure to substances from food contact materials and an introduction to the Facet Project	P.K.T Oldring	Deutsche Lebensmittel-Rundschau	Volume 105			29/09/2009	501-507		no
2	The Facet project: a chemical exposure surveillance system for Europe	A. Hearty	Food Science and Technology	Volume 25, issue 2			25/08/2011	26-29		no
3	Gaussian process emulation for second-order Monte Carlo simulations	J.J. Johnson	Journal Statistical Planning and Inference	Volume 141, issue 5	Elsevier		28/09/2011	1838-1848		yes
4	Sensitivity analysis and estimation of extreme tail behaviour in two-dimensional Monte Carlo simulation	V.J. Roelofs	Risk Analysis	Volume 31, Issue 10	Wiley		12/09/2011	1597-1609		no
5	Quantification of estragole in fennel herbal teas: Implications on the	A, Raffo, S. Nicoli, C. Leclercq	Food and Chemical Toxicology	Volume 49, Issue 2	Elsevier Ltd.	Netherlands	14/09/2011	370-375	DOI: http://dx.doi.org/10.1016/j.fct.2010.11.0.11	no

[2] A permanent identifier should be a persistent link to the published version full text if open access or abstract if article is pay per view) or to the final manuscript accepted for publication (link to article in repository).

[3] Open Access is defined as free of charge access for anyone via Internet. Please answer "yes" if the open access to the publication is already established and also if the embargo period for open access is not yet over but you intend to establish open access afterwards.

	assessmnet of dietary exposure to estragole.									
6	Quantification of allyl hexanoate in pineapple beverages and yogurts as a case study to characterize a source of uncertainty in dietary exposure assessment to flavouring substances.	A. D'Aloise, A.D. Magri, C. Leclercq	Food Additives & Contaminants (Part A)	No. 29 issue 1	Taylor and Francis	USA	18/04/2012	43-53	10.1080/19440049.2011.623285	no
7	Collection of chemical occurrence data for the exposure assessments of additive intakes in the Irish diet as part of a Pan-European chemical exposure surveillance system	A.M. Connolly	Proceedings of Nutrition Society	70(OCD3)	The Nutrition Society	London	30/08/2011	E68		Yes
8	New hierarchical classification of food items of exposure to packaging materials, use of hub codes for different food groups		Taylor & Francis Group	No 26 (4), April 2009	Food Additive & Contaminants Part A		2009	534 - 62		

TEMPLATE A2: LIST OF DISSEMINATION ACTIVITIES								
NO.	**Type of activities[4]**	**Main leader**	**Title**	**Date**	**Place**	**Type of audience[5]**	**Size of audience**	**Countries addressed**
1	Workshop	UNIVERSITY OF ULSTER	Facet food categorisation system	29/11/2010	Parma, Italy	Scientific community (higher education, Research)	20	EU
2	Workshop	P.K.T Oldring	ILSI Symposium on food contact materials	19/11/2008	Prague, Poland	Scientific community (higher education, Research) - Industry - Policy makers	400	EU, USA & Japan
3	Conference	P.K.T Oldring	SPI Annual Conference on regulatory aspects	03/12/2008	Charleston, USA	Industry	100	USA
4	Conference	P.K.T. Oldring	Pira conference on plastics and paper in contact with foodstuffs	10/12/2008	Brussels, Belgium	Scientific community (higher education, Research) - Industry - Policy	160	EU, USA & Asia

[4] A drop down list allows choosing the dissemination activity: publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other.

[5] A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias ('multiple choices' is possible.

						makers		
5	Conference	P.K.T. Oldring	Rapra conference on food contact materials	21/04/2009	Brussels, Belgium	Industry	50	EU
6	Conference	P.K.T. Oldring	VfV packaging for food	28/04/2009	Germany	Industry - Policy makers	85	EU
7	Workshop	P.K.T. Oldring	CCFRA food contact	07/05/2009	UK	Industry	60	EU
8	Conference	P.K.T. Oldring	PRN food food contact materials	10/06/2009	Brussels, Belgium	Industry - Policy makers	55	EU
9	Conference	P.K.T. Oldring	Pira conference on plastics and paper in contact with foodstuffs	10/12/2009	Dublin, Ireland	Scientific community (higher education, Research) - Industry - Policy makers	230	EU, USA & Asia
10	Conference	P.K.T. Oldring	Safefood	24/02/2010	Zeist, Netherlands	Scientific community (higher education, Research) - Industry - Policy makers	60	EU
11	Poster	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	Uncertainty in computer models (UCM) conference	12/07/2010	Sheffield, UK	Scientific community (higher education, Research)	60	UK
12	Poster	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	Royal Statistical Society Conference 2010	14/09/2010	Brighton, UK	Scientific community (higher education, Research)	200	UK
13	Workshop	P.K.T. Oldring	CCFRA food contact	30/09/2010	UK	Industry	50	EU
14	Conference	P.K.T. Oldring	Pira conference on plastics in contact with foodstuffs	09/12/2010	Berlin, Germany	Scientific community (higher	190	EEU, USA & Asia

						education, Research) - Industry - Policy makers		
15	Workshop	P.K.T. Oldring	EFSA-ESCO on non-plastic FCMs	10/03/2011	Milan, Italy	Scientific community (higher education, Research) - Policy makers	140	EU
16	Worksho	P.K.T. Oldring	MATRIX workshop organised by EuPC on NIAS	06/04/2011	Milan, Italy	Scientific community (higher education, Research) - Industry - Policy makers	100	EU
17	Workshop	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	Meeting with the Member State and Commission experts	05/05/2011	Brussels, Belgium	Policy makers	15	EU
18	Workshop	P.K.T. Oldring	CIAA workshop on exposure	07/06/2011	Brussels, Belgium	Industry - Policy makers	130	EU
19	Conference	P.K.T. Oldring	PRN conference on food contact materials	29/09/2011	Brussels, Belgium	Industry - Policy makers	80	EU
20	Conference	P.K.T. Oldring	Fresenius meeting on food packaging	17/10/2011	Cologne, Germany	Scientific community (higher education, Research) - Industry - Policy makers	200	EU
21	Conference	P.K.T. Oldring	Pira conference on plastics in contact with foodstuffs	06/12/2911	Rome , Italy	Scientific community (higher	240	EU, USA & Asia

						education, Research) - Industry - Policy makers		
22	Conference	P,K.T. Oldring	PRN conference on food contact materials	09/05/2012	Brussels, Belgium	Industry - Policy makers	80	EU
23	Conference	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	Fresenius conference on food packaging analysis	11/06/2012	Cologne, Germany	Scientific community (higher education, Research) - Industry - Policy makers	180	EU
24	Workshop	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	UK food Standards Agency: Risk Assessment and Mixtures Research Workshop 2012	09/10/2012	Coventry, UK	Scientific community (higher education, Research) - Policy makers	46	UK
25	Workshop	THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	Presentations to the UK-FSA Consumer Exposure Team (CERT) meetings	24/09/2012	London, UK	Scientific community (higher education, Research) - Policy makers	20	EU
26	Presentation	AGENCE NATIONALE DE SECURITE SANITAIRE DE L'ALIMENTATION, DE L'ENVIRONNEMENT ET DU TRAVAIL	Presentation of the Facet project: WG additives	04/03/2009	Paris, France	Industry	25	Francd
27	Presentation	AGENCE NATIONALE DE SECURITE SANITAIRE DE L'ALIMENTATION, DE L'ENVIRONNEMENT ET DU TRAVAIL	Presentation of the Facet project at the "Food improvement agents" committee annual meeting	16/11/2010	Brussels, Belgium	Industry	40	EU
28	Presentation	AGENCE NATIONALE DE	EFSA WG for exposure	17/05/2011	Brussels,	Policy	10	EU

		SECURITE SANITAIRE DE L'ALIMENTATION, DE L'ENVIRONNEMENT ET DU TRAVAIL			Belgium	makers		
29	Presentation	AGENCE NATIONALE DE SECURITE SANITAIRE DE L'ALIMENTATION, DE L'ENVIRONNEMENT ET DU TRAVAIL	Presentation of the Facet project at UNESDA meeting	23/09/2011	Paris, France	Industry	40	EU
30	Poster- presented at MoniQA International Conference	Raffo A., Ferrari M., Le Donne C., Paoletti F., Sette S., Engel K., Gibney M.J., Leclercq C.	"The new "FACET" (flavourings, Additives and Food Contact Material Exposure Task) project: Towards a more reliable assessment of dietary exposure to flavourings"	08/10/2008	Rome, Italy	Scientific community (higher education, Research) - Policy makers - Medias	300	International
31	Presentation - presented at workshop "Flavourings" COOP Itatlia	Leclercq C.	"La stima dell'esposizione ad additive, aroma e residui dei materiali da imballaggio (The dietary exposure assessment of additives, flavourings and residues of food contact materials within the procedure of food safety evaluation)	01/12/2009	Bologna, Italy	Food industry	30	Italy
32	Presentations – presented at workshop "Flavourings" COOP Italia	Leclercq C.	"Il progetto FACET: obiettivi e soggetti coinvolti (The Facet project: objectives and personnel involved)"	01/12/2009	Bologna, Italy	Food industry	30	Italy
33	Presentation – presented at workshop "Flavourings" COOP Italia	Leclercq C.	"Il ruolo dell'INRAN nel progetto FACET (WP2 – Flavourings: report on project progress)"	01/12/2009	Bologna, Italy	Food industry	30	Italy
34	Presentation – presented at	Le Donne C.	"Fonti di informazioni relative alla	01/12/2009	Bologna, Italy	Food industry	30	Italy

	workshop "Flavourings" COOP Italia		presenza/assenza di un aroma in un prodotto alimentare: categoria del prodotto, etichetta, informazioni date dal produttore (Flavourings occurrence in food: sources of information)"					
35	Presentation – presented at workshop "Flavourings" COOP Italia	Raffo A.	"Le 41 sostanze selezionate per una stima raffinata di esposizione nell'ambito del progetto FACET (The 41 falvouring substances selected within the FACET project)"	01/12/2009	Bologna, Italy	Food industry	30	Italy
36	Poster – presented at workshop "Flavourings" COOP Italia	Raffo A., Nicoli S., & Leclercq C.	Quantification of estrangole in commercial fennel teas & infusions by a simple & rapid SBSE-GC-MS method	13/04/2010	Eisenach, germany	Scientific community (higher education, Research) - Policy makers - Medias	300	International
37	Poster –presented at "QUARTO CONVEGNO GIOVANI La chimica nelle nanoscienze e nelle nanotechnologie" University "La Sapienza" of Rome – Department of Chemistry	D'Aloise A., Bucci R., Magri A., Raffo A., Leclercq C.	Sviluppo di un metodo rapido e semplice per la quantificazione di sostanze aromatizzanti aggfiunte alle bevande. Il caso dell'allil esanoato in bevande aromatizzate all'ananas	16/06/2010	Rome, Italy	Scientific community (higher education, Research)	150	Italy
38	Press release – INRAN	Leclercq C.	Quantification of estragole in fennel herbal teas: Implications on the assessment of dietary	20/12/2010	Rome, Italy	Scientific community (higher education, Research) -		Italy

			exposure to estragole.			Industry - Civil society - Policy makers - Medias		
39	Poster – presented at III Weuman Flavour Research Symposium	Raffo A., D'Aloise A., Magri D., Magri A.L., & Leclercq C.	Variability of allyl hexanoate concentration in pineapple-flavoured beverages and yogurts	27/09/2011	Zaragoza, Spain	Scientific community (higher education, Research) - Policy makers - Medias	300	International
40	Presentation at the Congress "Alimentazione, nutrizione e rete in Pediatria: dale parole ai fatti". Organized by the Paediatric Hopsital "Bambino Gesu".	Leclercq C.	Additivi ed aromi nei prodotti alimentari consumati nella prima infanzia	16/09/2011	Rome, Italy	Scientific community (higher education, Research)	100	Italy
41	Presentation at the meeting "Additivi alimentatri,quadro normative e sicurezza per la salute" organized by the Gruppo Scientifico Italiano Studi e RIcerche"	Leclercq C.	L'esposizione ad additivi e aromi nell"eta evolutiva. Additivi alimentari: quadro normativo e sicurezza per la salute.	10/05/2012	Milan, Italy	Scientific community (higher education, Research) - Industry	50	Italy
42	Conference	Prof. Vicente Ferreira (University of Zaragoza)	XIII. Weurman flavour research Symposium	27/09/2011	Zaragoza, Spain	Scientific community (higher education, Research)	300	International
43	Conference	Dr. Michael Granvogl (Lehrstuhl fûr Lebensmittelchemie, Technische Universtiät München).	Arbeitstagung des Regionalverbandes Bayern der Lebensmittelchemischen Gesellschaft.	19/04/2012	Dublin, Ireland	Scientific community (higher education, Research)	90	Germany

			Fachgruppe in					
44	Conference	Cronan McNamara (Creme)	Creme Exposure: Food Safety & Nutrition Conference	19/04/2012	Dublin, Ireland	Scientific community (higher education, Research)	110	International
45	Presentation	INNVENTIA AB	Customer Magazine Beyond	07/04/2008	Stockholm, Sweden	Industry - Policy makers - Medias	30	Sweden
46	Presentations	INNVENTIA AB	Presentation of the Facet project	22/11/2011	Stockholm, Sweden	Policy makers	30	Sweden
47	Presentations	KOZPONTI ELELMISZER-TUDOMANYI KUTATOINTEZET	Food additive content of bakery wares on the basis of the results of the Facet project	25/03/2011	Budapest, Hungary	Scientific community (higher education, Research) - Policy makers	50	Hungary
48	Workshop	CREME SOFTWARE LTD	Facet workshop for member states	05/05/2011	Brussels, Belgium	Policy makers	45	EU
49	Conference	CREME SOFTWARE LTD	ISES special session at the SETAC Europe Annual Meeting	18/05/2011	Milan, Italy	Scientific community (higher education, Research)	80	EU
50	Workshops	CREME SOFTWARE LTD	Managing variability and uncertainty in risk assessment and risk management	07/06/2011	Brussels, Belgium	Scientific community (higher education, Research)	50	EU
51	Presentations	CREME SOFTWARE LTD	European Commission meeting of the working party of governmental experts on flaourings	10/01/2012	Brussels, Belgium	Policy makers	40	EU
52	Presentations	CREME SOFTWARE LTD	FoodDrinkEurope Consumer Policy Meeting (FCPC)	16/02/2012	Brussels, Belgium	Industry	50	EU
53	Presentations	CREME SOFTWARE LTD	Expert Panel of The Flavour and Extract	22/05/2012	Dublin, Ireland	Industry	40	EU

			Manufacturers Association					
54	Workshops	CONFEDERATION DES INDUSTRIES AGRO-ALIMENTAIRES DE L'UE	Modeling workshop on "Managing Variability & Uncertainty in Risk Assessment & Risk Management	07/06/2011	Brussels, Belgium.	Scientific community (higher education, Research) - Industry - Policy makers	70	EU
55	Conference	JRC -JOINT RESEARCH CENTRE- EUROPEAN COMMISSION	Food factory 2012 6th international conference on food factory for the future	04/07/2012	Laval, France	Scientific community (higher education, Research) - Industry - Medias	100	EU
56	Press releases	ISTITUTO NAZIONALE DI RICERCA PER GLI ALIMENTI E LA NUTRIZIONE	Estragolo, http://www.inran.it (In website Estragolo is keyword to search the release	20/12/2010	Italy	Scientific community (higher education, Research) - Industry - Civil society - Policy makers - Medias		EU
57	Posters	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	Collection of chemical occurrence data for the exposure assessments of additive intakes in the Irish diet as part of a pan-European chemical exposure surveillance system.	17/06/2011	Cork, Ireland	Scientific community (higher education, Research) - Industry	120	EU, USA
58	Presentations	UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	Food additive content of bakery wares on the basis of the results of the Facet project	25/03/2011	Budapest, Hungary	Scientific community (higher education, Research)		EU
59	Posters	UNIVERSITY COLLEGE	The use of chemical	19/07/2012	Belfast,	Scientific	130	EU

		DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN	occurrence and concentration data in exposure assessments of additive intakes in the diets of Irish children as part of a pan-European chemical exposure surveillance system.		Northern Ireland	community (higher education, Research) - Industry		
60	Workshop	Dr. Peter Mercea – FABES GmbH	IVLV - Workgroup QSVL	08/06/2011	Freising, Germany	Scientific community (higher education, Research) - Industry	50	EU
61	Workshop	Dr. Peter Mercea – FABES GmbH	Facet -workshop of member states	05/05/2011	Brussels, Belgium	Scientific community (higher education, Research) - Industry	25	EU
62	Conference	Dr. Peter Mercea – FABES GmbH	EuPC - Conference	19/04/2012	Brussels, Belgium	Scientific community (higher education, Research) - Industry	45	EU, USE, Japan
63	Workshops	Dr. Peter Mercea – FABES GmbH	IVLV - workgroup QSVL	21/06/2912	Freising, Germany	Scientific community (higher education, Research) - Industry	40	EU

Table 1. Italian media and internet sites that disseminated the research on “Quantification of estragole in fennel herbal teas” in FACET project

Date	Type	Name/description
20.12.2010	NEWSFOOD.com; http://www.newsfood.com/q/6b59e753/tisane-al-finocchio-no-a-donne-incinte-e-bebe-sotto-i-4-anni/	Fennel herbal tea: no use for pregnant women and babies below 4 years (Tisane al finocchio, no a donne incinte e bebè sotto i 4 anni)
20.12.2010	Alimentazione Naturale. Il mangiar sano tra Tradizione e Scienza moderna. http://alimentazione-naturale.blogspot.com/2010/12/semi-di-finocchio-troppo-estragolo.html	Fennel seeds. Too much carcinogen estragole for babies and mothers (Semi di finocchio. Troppo estragolo cancerogeno per lattanti e mamme)
20.12.2010	News notizie salute; http://www.newnotizie.it/2010/12/20/tisane-al-finocchio-sconsigliate-nei-bambini-al-di-sotto-dei-4-anni/	Fennel herbal tea: It is not recommended to babies below 4 years and pregnant women (Tisane al finocchio: sconsigliate nei bambini al di sotto dei 4 anni e in gravidanza)
20.12.2010	ASCA – Italian news agency, Agenzia stampa quotidiana nazionale ; http://salute.asca.it/interna.php?articolo=SALUTE__ESTRAGOLO_NON_SICURO__TISANE_AL_FINOCCHIO_NON_RACCOMANDATE_PER_I_NEONATI&idnotizia=3057&sezione=news	HEALTH: Estragole not safe, fennel herbal tea it is not recommended to babies (SALUTE: Estragolo non sicuro, tisane al finocchio non raccomandate per i neonati)
20.12.2010	FIMMG Italian Family Doctor Association (Federazione Italiana Medici di Famiglia); http://old.fimmg.org/alimentazione/rassegna_stampa/articoli_rassegna_stampa/2010/dicembre/salute_inran.html	HEALTH: INRAN, Stop to fennel herbal tea, it contains harmful substance (SALUTE: INRAN, Alt a tisane finocchio, c'è sostanza nociva)
20.12.2010	FIMP – Italian Pediatrician Association (Federazione Italiana Medici Pediatri); http://www.fimp.org/notizieadn.aspx?id=5388	Food: INRAN, Fennel herbal tea: it is not recommended to babies and pregnant women (Alimenti: INRAN, tisane di finocchio sconsigliate a bebe' e future mamme)
20.12.2010	Paoblog – Blog on wordpress ; http://paoblog.wordpress.com/2010/12/20/tisane-finocchio-neonati/	Fennel herbal tea is not recommended to babies below 6 months…. (Sconsigliate le tisane a base di finocchio per neonati con meno di 6 mesi…)
21.12.2010	Il salvagente.it magazine online http://www.ilsalvagente.it/Sezione.jsp?idSezione=9139&lookfor=estragolo	Do not give Fennel herbal tea to babies: they are carcinogen. INRAN do not recommend the beverage to babies below 4 years: it contains estragole (Non date tisane al finocchio ai neonati: sono cancerogene. L'INRAN sconsiglia la bevanda fino ai 4 anni. Contiene estragolo)

Date	Type	Name/description
21.12.2010	Il sole 24 ore magazine online; http://salute24.ilsole24ore.com/articles/12367-estragolo-non-sicuro-tisane-al-finocchio-non-raccomandate	Estragole do not safe, fennel herbal tea is not recommended (Estragolo non sicuro, tisane al finocchio non raccomandate)
21.12.2010	Tutto mamma; website with news for new mothers http://www.tuttomamma.com/tisane-finocchio-tossiche-mamme-bambini/13168/	Fennel herbal tea harmful for pregnant women and babies (Tisane al finocchio tossiche per mamme e bambini)
21.12.2010	Genitori.it Il Moige - Movimento Italiano Genitori . website: new parent guide; http://www.genitori.it/documento.asp?sotto=10&articolo=13505	Fennel herbal tea? It is not recommended to babies (Tisane al finocchio? Sconsigliate ai bambini)
21.12.2010	Quotidiano sanità.it - quotidiano online di informazione sanitaria; magazine online on health http://www.quotidianosanita.it/scienza-e-armaci/articolo.php?articolo_id=2235	Fennel herbal tea: do not use it in babies (Tisane al finocchio: non usarle nei neonati)
21.12.2010	CEFARM ; Azienda farmaceutica – pharmaceutics company http://www.cefarm.it/scheda_news.php?id=280	Fennel herbal tea: do not use it in babies (Tisane al finocchio: non usarle nei neonati)
21.12.2010	Salute Newsletter. Magazine quotidiano di salute, medicina e benessere; magazine online on health http://www.salutenewsletter.org/estragolo-a-rischio-le-tisane/	Estragole, Fennel Herbal tea at risk. It is considered carcinogen the substance present in fennel seed (Estragolo, a rischio le tisane. La sostanza contenuta nei semi di finocchio è considerata cancerogena)
21.12.2010	Dire. Notiziario minori; News for children http://www.direnews.it/newsletter_minori/anno/2010/dicembre/21/?news=17	Fennel herbal tea? It is not recommended to babies (Tisane al finocchio? Sconsigliate ai bambini))
21.12.2010	Il farmacista online. It; website for chemist http://www.ilfarmacistaonline.it/scienza-e-farmaci/articolo.php?articolo_id=2235&&cat_1=5&&cat_2=0&&tipo=articolo	Fennel herbal tea; do not use it in babies (Tisane al finocchio: non usarle nei neonati)
21.12.2010	Movimento spontaneo farmacisti online. Per la difesa e la tutela della salute; website for chemist http://msfi.forumattivo.com/t506-studio-sconsiglia-tisane-al-finocchio-per-mamme-e-bambini	Research do not recommend the fennel herbal tea to pregnant women and babies (Studio sconsiglia tisane al finocchio per mamme e bambini)
21.12.2010	Spesa 2.0 Magazine; http://www.spesaduepuntozero.it/2010/12/salute-tisane-al-finocchio-non-sono-sicure-per-neonati-e-donne-incinte/	Health: Fennel Herbal tea is not safe to babies and pregnant women Salute: Tisane al finocchio non sono sicure per neonati e donne incinte

Date	Type	Name/description
22.12.2010	Mio bambino; website for new mothers http://www.miobambino.it/articolo/tisana-al-finocchio-no-grazie_859.html	Fennel herbal tea? No, thanks! (Tisana al finocchio? No grazie!)
23.12.2010	Lady blitz ; website for women http://www.ladyblitz.it/salute/2010-12-20-1451-nociva-tisana-finocchio-810890/	Harmful a substance present in fennel herbal tea. (Nociva una sostanza presente nelle tisane al finocchio)
28.12.2010	Well me.it ; website on fitness and health http://www.wellme.it/benessere/laltra-medicina/1995-tisane-al-finocchio-sconsigliate-a-donne-incinte-e-bambini-sotto-i-4-anni	Fennel herbal tea: it is not recommended to pregnant women and babies below 4 years (Tisane al finocchio: sconsigliate in gravidanza e nei bambini al di sotto dei 4 anni)
29.03.2011	Fiveoclock; blog http://justafiveoclocktea.com/tag/estragolo/	Fennel herbal tea to babies. Harmful or not? (Tisana al finocchio ai neonati. Tossica o no?
29.12.2010	Pagine mamma.it; website for new mothers http://www.paginemamma.it/it/581/news/nutrizione-e-scienze-dellalimentazione/detail_146241_tisane-al-finocchio-meglio-non-darle-ai-neonati.aspx?c1=25	Fennel herbal tea: do not give it to babies (Tisane al finocchio: meglio non darle ai neonati)
17.01.2011	Salute&Gusto - Periodico quindicinale - Editore Movimento Difesa del Cittadino Dir. - Anno II - n. 1 del 17.01.2011; magazine on citizen protection http://www.mdc.it/documenti/Salute&Gusto_n_1-2011.pdf	INRAN, Fennel herbal tea: hazard estragole (INRAN. Tisana al finocchio: pericolo estragolo)
25.01.2011	Quotidiano di informazione. Riviera oggi; magazine online http://www.rivieraoggi.it/2011/01/25/111870/tisane-al-finocchio-no-in-gravidanza-allattamento-e-bambini-sotto-i-4-anni/	Fennel herbal tea: It is not recommended to pregnant women, lactating women and babies below 4 years (Tisane al finocchio: no in gravidanza, allattamento e bambini sotto i 4 anni)
25.01.2011	"La Repubblica " - newspaper	Fennel herbal teas are not recommended to babies (Le tisane di finocchio sconsigliate ai bambini)
27.01.2011	Guide genitori. It; website for new parents http://www.guidagenitori.it/HomePage.aspx?IDArticolo=2024&Area=Tisane%20al%20finocchio	Fennel herbal teas (Tisane al finocchio)
28.01.2011	Consumer - il portale dei consumatori; ER il	Fennel herbal teas (Tisane al finocchio)

Date	Type	Name/description
	portale della regione Emilia Romagna; website for consumer http://www.ermesconsumer.it/news/pagina654.html	
01.02.2011	"Occhio alla spesa" TV interview to Antonio Raffo **Video available at:** http://www.rai.tv/dl/RaiTV/programmi/media/ContentItem-77337ae9-d32e-4d8f-b83a-659a3911e9ad.html minute: 33:57	Fennel herbal tea: hazard estragole (Tisana al finocchio: pericolo estragolo)
02.07.2011	Europass - EFSA - Rassegna Stampa; Europass press review http://www.europass.parma.it/page.asp?IDCategoria=553&IDSezione=0&ID=417325	Fennel herbal tea contains estragole: a harmful substance and carcinogen, it is to be avoided (Le tisane al finocchio contengono l'estragolo: una sostanza tossica e cancerogena, da evitare)
03.02.2011	saicosatispalmi FORUM. i cosmetici, l'ambiente e tutto il resto; website of fitness, environment and other http://forum.saicosatispalmi.org/viewtopic.php?t=14185&sid=5b7426f000d4f3eb34262934fad2a139	Red alert to fennel herbal teas. These beverages contain estragole, a potential carcinogen. Babies are more exposed (Tisane al finocchio scatta l'allarme rosso. Questi infusi contengono estragolo, un potenziale cancerogeno. Più esposti i bimbi)
06.01.2011	Europass - EFSA - rassegna stampa; Europass press review http://www.europass.parma.it/page.asp?IDCategoria=553&IDSezione=0&ID=389828	Red alert to fennel herbal teas. These beverages contain estragole, a potential carcinogen. Babies are more exposed (Tisane al finocchio scatta l'allarme rosso. Questi infusi contengono estragolo, un potenziale cancerogeno. Più esposti i bimbi)
14.03.2011	Kataweb ; http://canali.kataweb.it/kataweb-consumi/2011/03/14/tisane-per-i-bimbi-no-al-finocchio-fino-a-4-anni/?printpage=undefined	Herbal tea to babies. No to fennel herbal teas for babies below 4 years (Tisane per i bimbi. No al finocchio, fino a 4 anni)
14.06.2011	Dieta e DNA newsletter; http://www.dietaedna.it/news.asp?R_MULTI_URL=%7Cid_grupponews%A76%7Cid_news%A713%7C	Alarm sign for fennel herbal teas (Campanello d'allarme per le tisane al finocchio)
15.06.2011	L'opinione n. 11, pag. 10 - Section "Medicina e dintorni" – online magazine http://www.teleibs.it/lopinione/2011/11_lopinione_15_06_2011.pdf	Fennel herbal tea: INRAN research on Estragole published on “Food and Chemical Toxicology” (Tisana di finocchio: studio INRAN sull’Estragolo pubblicato su “Food and Chemical Toxicology”)
28.03.2011	"Occhio alla spesa" TV interview to Antonio Raffo	Babies: Attention to fennel herbal teas (Neonati: attenzione alle tisane al finocchio)

Date	Type	Name/description
	"RAI TG1" ore 20.00 (RAI news) TV interview to Catherine Leclercq **Video available at:** http://www.rai.tv/dl/RaiTV/programmi/media/ContentItem-7f069032-24a3-4d73-a3e2-4b371e07b1d5-tg1.html minute: 33:58	
30.03.2011	Fondazione Umberto Veronesi. Per il progresso delle scienze; Healthy Organization http://www.fondazioneveronesi.it/la-tua-salute/587	Babies, fennel herbal teas have not always health benefits (Neonati, non sempre le tisane sono un toccasana)
March/April 2011	"Il giornale del consumatore" Anno XXIV n. 223 pag. 39 ; magazine online http://www.ilconsumatore.eu/wp-content/uploads/2008/04/ILCONSU_223.pdf	An INRAN research on estragole (Uno studio dell'INRAN sull'estragolo)
on the web	Gravidanza web.it – website for pregnant women; http://www.gravidanzaweb.it/gravidanza_news_tisane_al_finocchio23_no_a_donne_incinte_e_bebe_sotto_i_4_anni22.htm	Fennel herbal teas, do not give to pregnant women and babies below 4 years (Tisane al finocchio, no a donne incinte e bebè sotto i 4 anni)
on the web	Elation blog; http://blog.elation.it/1585/tisane-per-i-bimbi-no-al-finocchio-fino-a-4-anni/	Herbal tea to babies. No to fennel herbal teas for babies below 4 years (Tisane per i bimbi. No al finocchio, fino a 4 anni)

Section B (Confidential[6] or public: confidential information to be marked clearly)
Part B1

The applications for patents, trademarks, registered designs, etc. shall be listed according to the template B1 provided hereafter.

TEMPLATE B1: LIST OF APPLICATIONS FOR PATENTS, TRADEMARKS, REGISTERED DESIGNS, ETC.					
Type of IP Rights[7]:	Confidential Click on YES/NO	Foreseen embargo date dd/mm/yyyy	Application reference(s) (e.g. EP123456)	Subject or title of application	Applicant (s) (as on the application)

[6] Note to be confused with the "EU CONFIDENTIAL" classification for some security research projects.

[7] A drop down list allows choosing the type of IP rights: Patents, Trademarks, Registered designs, Utility models, Others.

TEMPLATE B2: OVERVIEW TABLE WITH EXPLOITABLE FOREGROUND

Type of Exploitable Foreground[8]	Description of exploitable foreground	Confidential Click on YES/NO	Foreseen embargo date dd/mm/yyyy	Exploitable product(s) or measure(s)	Sector(s) of application[9]	Timetable, commercial or any other use	Patents or other IPR exploitation (licences)	Owner & Other Beneficiary(s) involved
General advancement of knowledge	*Dietary exposure software source code*	*YES*		*Exposure software products*	*Food and Chemical exposure sector*			*Creme Software owns dietary exposure software source code.*
General advancement of knowledge	*Dietary exposure software tool*	*NO*		*Freely available Exposure Software product*	*Food Industry Food Additives Flavourings Food packaging Regulators*			*Creme Software owns dietary exposure software source code. FABES owns migration modelling software code that is used inside of dietary exposure.*
General advancement of knowledge	*New food chemical and food intake databases inside software*	*No for flavourings, Yes for all others*		*Freely available databases as part of software product*	*Food Industry Food Additives Flavourings Food packaging Regulators*			*Member states and Industry who provided data*

In addition to the table, please provide a text to explain the exploitable foreground, in particular:

[19] A drop down list allows choosing the type of foreground: General advancement of knowledge, Commercial exploitation of R&D results, Exploitation of R&D results via standards, exploitation of results through EU policies, exploitation of results through (social) innovation.

[9] A drop down list allows choosing the type sector (NACE nomenclature) : http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

ADDITIONAL TEMPLATE B2: OVERVIEW TABLE WITH EXPLOITABLE FOREGROUND

Dietary exposure software source code

To estimate dietary exposure to flavourings, additives and food contact materials in European Consumers.

Dietary exposure software tool

The software will be freely available for download on the Joint Research Centre website, by regulators, industry, NGOs and the general public.

New food chemical and food intake databases inside software

Optimisation and refinement of exposure models and algorithms is required. This is to speed up run time of the calculations and improvement of the accuracy of the calculations.?For the first time, a harmonised approach to calculating dietary exposure ineight member states will be freely available in Europe.

4.2 Report on societal implications

Replies to the following questions will assist the Commission to obtain statistics and indicators on societal and socio-economic issues addressed by projects. The questions are arranged in a number of key themes. As well as producing certain statistics, the replies will also help identify those projects that have shown a real engagement with wider societal issues, and thereby identify interesting approaches to these issues and best practices. The replies for individual projects will not be made public.

A General Information *(completed automatically when **Grant Agreement number** is entered.*	
Grant Agreement Number:	**211686**
Title of Project:	**Flavours, additives and food contact material exposure task**
Name and Title of Coordinator:	**Professor Michael Gibney**

B Ethics	
1. Did your project undergo an Ethics Review (and/or Screening)? • If Yes: have you described the progress of compliance with the relevant Ethics Review/Screening Requirements in the frame of the periodic/final project reports? Special Reminder: the progress of compliance with the Ethics Review/Screening Requirements should be described in the Period/Final Project Reports under the Section 3.2.2 *'Work Progress and Achievements'*	***X Yes***
2. Please indicate whether your project involved any of the following issues (tick box) :	***YES***
RESEARCH ON HUMANS	
• Did the project involve children?	No
• Did the project involve patients?	No
• Did the project involve persons not able to give consent?	No
• Did the project involve adult healthy volunteers?	Yes
• Did the project involve Human genetic material?	No
• Did the project involve Human biological samples?	No
• Did the project involve Human data collection?	Yes
• Did the project involve Human Embryos?	No
• Did the project involve Human Foetal Tissue / Cells?	No
• Did the project involve Human Embryonic Stem Cells (hESCs)?	No
• Did the project on human Embryonic Stem Cells involve cells in culture?	No
• Did the project on human Embryonic Stem Cells involve the derivation of cells from Embryos?	No
PRIVACY	
• Did the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	No
• Did the project involve tracking the location or observation of people?	No
RESEARCH ON ANIMALS	
• Did the project involve research on animals?	No
• Were those animals transgenic small laboratory animals?	No

• Were those animals transgenic farm animals?	No
• Were those animals cloned farm animals?	No
• Were those animals non-human primates?	No
RESEARCH INVOLVING DEVELOPING COUNTRIES	
• Did the project involve the use of local resources (genetic, animal, plant etc)?	No
• Was the project of benefit to local community (capacity building, access to healthcare, education etc)?	No
DUAL USE	
• Research having direct military use	No
• Research having the potential for terrorist abuse	No

C Workforce Statistics

3. Workforce statistics for the project: Please indicate in the table below the number of people who worked on the project (on a headcount basis).

Type of Position	Number of Women	Number of Men
Scientific Coordinator	0	1
Work package leaders	5	3
Experienced researchers (i.e. PhD holders)	22	20
PhD Students	4	2
Other	28	23

4. How many additional researchers (in companies and universities) were recruited specifically for this project?	**261**
Of which, indicate the number of men:	225

D Gender Aspects

5. Did you carry out specific Gender Equality Actions under the project?	○ X	Yes No

5. Which of the following actions did you carry out and how effective were they?

	Not applicable	Not at all effective				Very effective
❑ Design and implement an equal opportunity policy		○	○	○	○	○
❑ Set targets to achieve a gender balance in the workforce		○	○	○	○	○
❑ Organise conferences and workshops on gender		○	○	○	○	○
❑ Actions to improve work-life balance		○	○	○	○	○
○ Other:						

7. Was there a gender dimension associated with the research content – i.e. wherever people were the focus of the research as, for example, consumers, users, patients or in trials, was the issue of gender considered and addressed?

○ Yes- please specify

X No

E Synergies with Science Education

8. Did your project involve working with students and/or school pupils (e.g. open days, participation in science festivals and events, prizes/competitions or joint projects)?

○ Yes- please specify

X No

9. Did the project generate any science education material (e.g. kits, websites, explanatory booklets, DVDs)?

○ Yes- please specify

X No

F Interdisciplinarity

10. Which disciplines (see list below) are involved in your project?

○ Main discipline[10]:

○ Associated discipline[10]:

X Health Science

X Chemical Science

X Mathematics & computer Science

○ Associated discipline[10]:

G Engaging with Civil society and policy makers

11a Did your project engage with societal actors beyond the research community? *(if 'No', go to Question 14)*	X ○	Yes No

11b If yes, did you engage with citizens (citizens' panels / juries) or organised civil society (NGOs, patients' groups etc.)?

X No

[10] Insert number from list below (Frascati Manual).

○ Yes- in determining what research should be performed ○ Yes - in implementing the research ○ Yes, in communicating /disseminating / using the results of the project		
11c In doing so, did your project involve actors whose role is mainly to organise the dialogue with citizens and organised civil society (e.g. professional mediator; communication company, science museums)?	○ Yes X No	
12. Did you engage with government / public bodies or policy makers (including international organisations)		
X No ○ Yes- in framing the research agenda ○ Yes - in implementing the research agenda ○ Yes, in communicating /disseminating / using the results of the project		
13a Will the project generate outputs (expertise or scientific advice) which could be used by policy makers? X Yes – as a **primary** objective (please indicate areas below- multiple answers possible) ○ Yes – as a **secondary** objective (please indicate areas below - multiple answer possible) ○ No		

13b If Yes, in which fields?

Agriculture		Energy		Human rights	
Audiovisual and Media		Enlargement		Information Society	
Budget		Enterprise		Institutional affairs	
Competition		Environment		Internal Market	
Consumers	X	External Relations		Justice, freedom and security	
Culture		External Trade		Public Health	X
Customs		Fisheries and Maritime Affairs		Regional Policy	
Development Economic and Monetary Affairs		Food Safety	X	Research and Innovation	
Education, Training, Youth		Foreign and Security Policy		Space	
Employment and Social Affairs		Fraud		Taxation	
		Humanitarian aid		Transport	

13c If Yes, at which level?

- ○ Local / regional levels
- ○ National level
- ○ European level
- X International level

H Use and dissemination

14. How many Articles were published/accepted for publication in peer-reviewed journals?	
To how many of these is open access[11] provided?	**2**
How many of these are published in open access journals?	**0**
How many of these are published in open repositories?	**0**
To how many of these is open access not provided?	**5**
Please check all applicable reasons for not providing open access:	
❑ publisher's licensing agreement would not permit publishing in a repository ❑ no suitable repository available ❑ no suitable open access journal available ❑ no funds available to publish in an open access journal ❑ lack of time and resources ❑ lack of information on open access ❑ other[12]: ……	

15. How many new patent applications ('priority filings') have been made? *("Technologically unique": multiple applications for the same invention in different jurisdictions should be counted as just one application of grant).*		**0**
16. Indicate how many of the following Intellectual Property Rights were applied for (give number in each box).	Trademark	**0**
	Registered design	**0**
	Other	**0**
17. How many spin-off companies were created / are planned as a direct result of the project?		**0**
Indicate the approximate number of additional jobs in these companies:		

18. Please indicate whether your project has a potential impact on employment, in comparison with the situation before your project:

❑	Increase in employment, or	❑	In small & medium-sized enterprises
X	Safeguard employment, or	X	In large companies
❑	Decrease in employment,	❑	None of the above / not relevant to the project
❑	Difficult to estimate / not possible to quantify		

19. For your project partnership please estimate the employment effect resulting directly from your participation in Full Time Equivalent (*FTE = one person working fulltime for a year*) jobs:	*Indicate figure:* *0*

[11] Open Access is defined as free of charge access for anyone via Internet.
[12] For instance: classification for security project.

Difficult to estimate / not possible to quantify	❑

I Media and Communication to the general public

20. As part of the project, were any of the beneficiaries professionals in communication or media relations?

X Yes ○ No

21. As part of the project, have any beneficiaries received professional media / communication training / advice to improve communication with the general public?

○ Yes X No

22 Which of the following have been used to communicate information about your project to the general public, or have resulted from your project?

X	Press Release	X	Coverage in specialist press
❑	Media briefing	X	Coverage in general (non-specialist) press
X	TV coverage / report	X	Coverage in national press
X	Radio coverage / report	❑	Coverage in international press
X	Brochures /posters / flyers	X	Website for the general public / internet
❑	DVD /Film /Multimedia	❑	Event targeting general public (festival, conference, exhibition, science café)

23 In which languages are the information products for the general public produced?

❑	Language of the coordinator	X	English
❑	Other language(s)		

***Question F-10*:** Classification of Scientific Disciplines according to the Frascati Manual 2002 (Proposed Standard Practice for Surveys on Research and Experimental Development, OECD 2002):

FIELDS OF SCIENCE AND TECHNOLOGY

1. NATURAL SCIENCES

1.1 Mathematics and computer sciences [mathematics and other allied fields: computer sciences and other allied subjects (software development only; hardware development should be classified in the engineering fields)]

1.2 Physical sciences (astronomy and space sciences, physics and other allied subjects)

1.3 Chemical sciences (chemistry, other allied subjects)

1.4 Earth and related environmental sciences (geology, geophysics, mineralogy, physical geography and other geosciences, meteorology and other atmospheric sciences including climatic research, oceanography, vulcanology, palaeoecology, other allied sciences)

1.5 Biological sciences (biology, botany, bacteriology, microbiology, zoology, entomology, genetics, biochemistry, biophysics, other allied sciences, excluding clinical and veterinary sciences)

2 ENGINEERING AND TECHNOLOGY

2.1 Civil engineering (architecture engineering, building science and engineering, construction engineering, municipal and structural engineering and other allied subjects)

2.2 Electrical engineering, electronics [electrical engineering, electronics, communication engineering and systems, computer engineering (hardware only) and other allied subjects]

2.3. Other engineering sciences (such as chemical, aeronautical and space, mechanical, metallurgical and materials engineering, and their specialised subdivisions; forest products; applied sciences such as

geodesy, industrial chemistry, etc.; the science and technology of food production; specialised technologies of interdisciplinary fields, e.g. systems analysis, metallurgy, mining, textile technology and other applied subjects)

3. MEDICAL SCIENCES

3.1 Basic medicine (anatomy, cytology, physiology, genetics, pharmacy, pharmacology, toxicology, immunology and immunohaematology, clinical chemistry, clinical microbiology, pathology)

3.2 Clinical medicine (anaesthesiology, paediatrics, obstetrics and gynaecology, internal medicine, surgery, dentistry, neurology, psychiatry, radiology, therapeutics, otorhinolaryngology, ophthalmology)

3.3 Health sciences (public health services, social medicine, hygiene, nursing, epidemiology)

4. AGRICULTURAL SCIENCES

4.1 Agriculture, forestry, fisheries and allied sciences (agronomy, animal husbandry, fisheries, forestry, horticulture, other allied subjects)

4.2 Veterinary medicine

5. SOCIAL SCIENCES

5.1 Psychology

5.2 Economics

5.3 Educational sciences (education and training and other allied subjects)

5.4 Other social sciences [anthropology (social and cultural) and ethnology, demography, geography (human, economic and social), town and country planning, management, law, linguistics, political sciences, sociology, organisation and methods, miscellaneous social sciences and interdisciplinary , methodological and historical S1T activities relating to subjects in this group. Physical anthropology, physical geography and psychophysiology should normally be classified with the natural sciences].

6. HUMANITIES

6.1 History (history, prehistory and history, together with auxiliary historical disciplines such as archaeology, numismatics, palaeography, genealogy, etc.)

6.2 Languages and literature (ancient and modern)

6.3 Other humanities [philosophy (including the history of science and technology) arts, history of art, art criticism, painting, sculpture, musicology, dramatic art excluding artistic "research" of any kind, religion, theology, other fields and subjects pertaining to the humanities, methodological, historical and other S1T activities relating to the subjects in this group]