SEVENTH FRAMEWORK PROGRAMME
THEME 2
Food, Agriculture and Fisheries, and Biotechnology

Grant agreement for: *Large Collaborative Project*

Annex I - "Description of Work"

Project acronym: *FACET*

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

Grant agreement no.: *211686*

Date of preparation of Annex I (latest version): 7th July 2008

Date of approval of Annex I by Commission: *(to be completed by Commission)*

Structure of Annex 1

Glossary

ADI	Acceptable Daily Intake
AFC	The Scientific Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food
CAS No	A numerical identifier for chemical compounds, polymers, biological sequences, mixtures and alloys.
CCFAC	Codex Committee on Food Additives and Contaminants
DAFNE	Data Food Networking Project
EFFA	European Flavour and Fragrance Association
EFSA	European Food Safety Authority
EU	European Union
FACET	Flavourings, Additives and Food Contact Material Exposure Task
FAO	Food and Agriculture Organisation
WHO	World Health Organisation
FCM	Food Contact Materials
FFQ	Food Frequency Questionnaire
FGE	Flavouring Group Evaluation
FTIR	Fourier Transform Infra Red
GC-MS	Gas Chromatography – Mass Spectroscopy
GSFA	General Standards for Food Additives
HEIMSTA	Health and Environment Integrated Methodology and Toolbox for Scenario Assessment
IP	Intellectual Property
ILSI	International Life Science Institute
INFID	Irish National Food Ingredient Database
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC-MS	Liquid Chromatography – Mass Spectroscopy
LOAEL	Lowest Observable Adverse Effect Level
MGM	Management
ML	Multilayer (packaging)
MSDI	Maximised Survey-Derived Daily Intakes
MTAMDI	Modified Theoretical Added Maximum Daily Intake
NIAS	Not Intentionally Added Substances
NOAEL	No Observed Adverse Effect Level
NSIFCS	North South Ireland Food Consumption Survey
PA	Polyamide
PET	Polyethylene Terephthalate
PO	Polyolefin
PS	Polystyrene
QSAR	Quality Structure Activity Relationship
RTD	Research and Technological Development
SCOOP	Scientific Cooperation
SME	Small Medium Enterprise
TAMDI	Theoretical Added Maximum Daily Intake
TTC	Threshold of Toxicological Concern

Part A

A1. Budget breakdown and project summary

A.1 Overall budget breakdown for the project

Participant number in this project [9]	Participant short name	Estimated eligible costs (whole duration of the project)					Total receipts	Requested EC contribution
		RTD / Innovation (A)	Demonstration (B)	Management (C)	Other (D)	Total A+B+C+D		
1	NUID UCD	274,493.00	0.00	327,987.00	92,013.00	694,493.00	0.00	625,870.00
2	UU	359,446.00	0.00	0.00	0.00	359,446.00	0.00	269,585.00
3	CSL	966,825.00	0.00	2,000.00	0.00	968,825.00	0.00	727,119.00
4	CEPE	920,813.00	0.00	0.00	0.00	920,813.00	400,000.00	0.00
5	FCRA	157,899.00	0.00	0.00	0.00	157,899.00	0.00	118,424.00
6	AFSSA	555,093.00	0.00	0.00	0.00	555,093.00	0.00	416,114.00
7	INRAN	712,549.00	0.00	3,000.00	0.00	715,549.00	0.00	537,412.00
8	TUM	248,597.00	0.00	0.00	0.00	248,597.00	0.00	186,448.00
9	FABES	258,508.00	0.00	0.00	0.00	258,508.00	0.00	129,254.00
10	Fraunhofer	513,772.00	0.00	2,250.00	0.00	516,022.00	0.00	387,579.00
11	KTL	313,171.00	0.00	0.00	0.00	313,171.00	0.00	234,878.00
12	STFI-Packforsk	571,032.00	0.00	1,000.00	0.00	572,032.00	0.00	429,274.00
13	CFRI	107,480.00	0.00	0.00	0.00	107,480.00	0.00	80,610.00
15	Creme	862,006.00	0.00	3,000.00	14,400.00	879,406.00	0.00	663,905.00
16	USC	181,910.00	0.00	0.00	0.00	181,910.00	0.00	136,433.00
17	IZZ	96,510.00	0.00	0.00	0.00	96,510.00	0.00	72,383.00
18	INCDTIM	75,571.00	0.00	0.00	0.00	75,571.00	0.00	56,678.00
19	CIAA (AISBL)	344,939.00	0.00	0.00	0.00	344,939.00	0.00	258,704.00
21	JRC.IHCP	533,413.00	0.00	5,760.00	0.00	539,173.00	0.00	405,820.00
22	FCNAUP	199,486.00	0.00	0.00	0.00	199,486.00	0.00	149,615.00
TOTAL		8,253,513.00	0.00	344,997.00	106,413.00	8,704,923.00	400,000.00	5,886,105.00

A.2 Project summary

GENERAL INFORMATION			
Project title [3]	Flavours, additives and food contact material exposure task		
Starting date [4]	The first day of the month after the signature by the Commission		
Duration in months [5]	48		
Call (part) identifier [6]	FP7-KBBE-2007-1		
Activity code(s) most relevant to your topic [7]	KBBE-2007-2.4-01: Exposure to food additives, flavourings, and migrants coming from the food contacts materials Dietary intake models	KBBE-2007-2.4-02: Detecting contaminants in the food and feed chain	
Free keywords [8]		Food chemical exposure; additives; flavouring; packaging; food chemical occurrence; probabilistic modeling	
Abstract [9] (max. 2000 char.)			

Flavouring, Additive and Food Contact Material Exposure Task: FACET FACET will deliver to the European Community a sustainable surveillance system, to estimate target food chemical intake. The project will consist of three main groupings of its 20 partners. The "Chemicals" group will prioritise the flavourings, additives and food contact materials for investigation and the food categories applicable to them. The "Food" group will take those food categories and will establish food ingredient occurrence data through the primary collection of food packaging material and the recording of all food ingredients in purchased foods. It will also create tired food consumption databases linked to the target food categories. In addition, where intake data is limited, models of regional diets will be developed. A group on chemical concentration will provide data on the concentration of target chemicals in target food groups. Databases on food intake, food chemical occurrence and food chemical concentration will be linked in algorithms which will be converted into computer code for the estimation of probabilistic exposure to target food chemical intake.

A.3 List of beneficiaries

List of Beneficiaries

Beneficiary Number*	Beneficiary name	Beneficiary short name	Country	Date enter project**	Date exit project**
1(coordinator)	University College Dublin	UCD	Ireland	Month 1	Month 48
2	University of Ulster	UU	UK	Month 1	Month 48
3	Central Science Laboratory	CSL	UK	Month 1	Month 48
4	European Council of the Paint, Printing Ink and Artists Colours Industry	CEPE	Belgium	Month 1	Month 48
5	Food Chemical Risk Assessment Ltd	FCRA	UK	Month 1	Month 48
6	Agence Française de Sécurité, Sanitaire des Produits de Santé	AFSSA	France	Month 1	Month 48
7	National Institute for Food and Nutrition Research	INRAN	Italy	Month 1	Month 48
8	Technical University of Munich	TUM	Germany	Month 1	Month 48
9	FABES Ltd	FABES	Germany	Month 1	Month 48
10	Fraunhofer Institut für Verfahrenstechnik und Verpackung	Fraunhofer	Germany	Month 1	Month 48
11	National Public Health Institute	KTL	Finland	Month 1	Month 48
12	STFI-Packforsk	STFI	Sweden	Month 1	Month 48
13	Central Food Research Institute	CFRI	Hungary	Month 1	Month 48
15	CREMe Software Ltd.	CREME	Ireland	Month 1	Month 48
16	University of Santiago de Compostela	USC	Spain	Month 1	Month 48
17	National Food and Nutrition Institute	IZZ	Poland	Month 1	Month 48
18	National Institute for Research and Development of Isotopic and Molecular Technologies	INCDTIM	Romania	Month 1	Month 48
19	Confédération des Industries agro-Alimentaire	CIAA	Belgium	Month 1	Month 48
21	Joint Research Centre	JRC	Italy	Month 1	Month 48
22	Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto	FCNAUP	Portugal	Month 1	Month 48

*Note: There is no partner 20 as the original partner 20 left before the official start date of the project

Part B

B1. Concept and objectives, progress beyond state-of-the-art, S/T methodology and work plan

The *concept* behind this project is the creation of a food chemical exposure surveillance system, sustainable beyond the life of the project, which covers representative regions of the EU and which meets, to the highest possible standard, the needs of the EU regulatory authorities in the protection of consumer health. In order to ensure continuity after the finish of the project, those partners (CSL, CRÈME, 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 (partner 21).
The *main ideas* that led to the present consortium project are summarised as follows:

- Efforts to monitor exposure to food chemical intake tend to be orientated toward specific groups of chemicals and to date, no concerted effort has been made in the EU *to combine exposure estimates for several chemicals into one project*. This is likely to maximise success rates where requests to national food database managers can be streamlined and coordinated
- In the past, individual projects estimating food chemical exposure have had a finite objective in providing an exposure estimate at a defined point in time. The present study will certainly do that but it is also intended that the surveillance system developed in the present project *will be capable of being both sustained and developed* for use by EU regulatory authorities.

The *S&T objectives* are as follows:

1. To record occurrence levels of targeted chemicals in representative regions of the EU food supply. This will include a major survey of food packaging usage in countries representative of the regional groupings of FACET.
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– it is a specific requirement of the Call Topic to introduce the concept of QSAR (Quantitative Structure Activity Relationships) into the migration models.
4. To construct a tiered food intake database aimed at foods which are relevant to the target food chemicals. The database will be tiered from very comprehensive data to less detailed data to reflect the existing variability in the access to, and level of detail in, food intake data.
5. To develop a PC based, publicly available software programme, taking in to account the variation of national food consumption data, which will draw on limited data, build on known laws governing food intake and in particular build on small national surveys and local knowledge to model regional intake of target foods.
6. Finally, to build new databases, populate them with the data generated by the project and to estimate exposure assessment using a probabilistic model. The default for this model will be the existing conservative values and the model will be built so that these conservative values can be replaced by real data gathered in the field. This will facilitate probabilistic estimates of exposure assessment.

B.1.2 Progress beyond the state of the art

An overview of the present state of the art for food chemical exposure studies

The European Food Safety Authority's (EFSA) Scientific Committee has expressed an Opinion on exposure assessments used to support its work[1]. They noted that internationally accepted guidance exists in most areas of EFSA's work where exposure assessment is required and recommended that EFSA Panels use established guidance which has the advantage of increasing acceptance and comparison of the EFSA assessments internationally. The Joint FAO/WHO Secretariat of the JECFA has laid down guidelines for intake estimation (FAO/WHO Joint Secretariat, 2001)[2]. These guidelines follow a tiered approach, in which simple, conservative screening methods are used to provide initial intake estimates and which are gradually refined using national production figures and finally individual food consumption data. A tiered approach was also adopted in the EU Commission's report on Dietary Food Additive Intake in the European Union (the 'SCOOP 4.2' report)[3]:

There are some basic principles for the assessment of exposure to food additives. The first basic principle is that any assessment of exposure should begin with crude screening methods where worst case assumptions are made. (e.g. the "Budget method" and the "Back calculation method"). Where such crude screening methods indicate that the reference intake value will not be exceeded, then the process ends. Otherwise one moves to the next step in this tiered approach i.e. the Step 1 approach[2]. This takes the average daily food consumption of each food category in which an additive can be present and multiplies this by the maximum permitted level for that food category. The sum of these products is taken to represent a conservative estimate of exposure to the target chemical. Again, if exposure estimates using this methods fall below the reference Acceptable Daily Intake (ADI) then the process can stop. However, if the value for intake exceeds the ADI, then a move to the next level of the tier is necessitated i.e. the Step 2 approach[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. Thus a distribution of the intakes of all individuals is computed and the exposure at some upper percentile is used to compare with the ADI. This still remains a conservative approach because it assumes that if an additive is legally present in a food then it will be present with a probability of 100% and that when present, it is always present at the maximum permitted level. We know from research that these two assumptions are not valid as many national surveys have shown that the concentrations of additives in foods are never 100% at the legal maximum level[4]. In the case of flavouring compounds and packaging migrants, the basic principles outlined for additives also apply although acquiring data on occurrence and concentration poses far greater challenges as is outlined in ensuing sections. For example, there is no legal definition of where in the food supply food contact materials or flavourings can be used and there is no published reference toxicological value such as an ADI against which an exposure estimate can be made.

[1] European Food Safety Authority (2005). Opinion of the Scientific Committee on a request from EFSA related to Exposure Assessments. (Request No EFSA-Q-2003-107), adopted on 22 June 2005. The EFSA Journal (2005) 249, 1-26.

[2] FAO/WHO Joint Secretariat (2001). Guidelines for the preparation of working papers on intake of food additives for the Joint FAO/WHO Expert Committee on Food Additives. Geneva.

[3] Report from the Commission on Dietary Food Additive Intake in the European Union, 01 October 2001.

[4] Leht T, Fabricius B, Fagt S (2007) Estimated intake of intense sweeteners from non-alcoholic beverages in Denmark, Food Addit Contam, March, 24(3), 227-35

The assessment of exposure to food chemicals using probabilistic modeling is receiving increasing attention and this was the subject of a large collaborative project in the 5th Framework Programme[5]. The Step 2 approach as outlined is deterministic in that it assumes a fixed value for the probability that a food might contain an approved additive (100%) and a fixed value for chemical concentration (maximum legal level). Since neither of these is usually true, when the appropriate data are available, probabilistic modeling can be conducted. The minimum data that are needed are:

- The probability that a food might contain the additive (occurrence data)
- The intake of the food at individual level or probability distribution level (food intake data)
- The probability distribution for food chemical concentration (concentration data)

In ensuing sections specifics of the state of the art and beyond are described in relation to the main research areas of the project: additives, flavourings, packaging material migratory compounds, food chemical occurrence data, food chemical concentration data, food intake data, regional modeling and modeling exposure assessment.

(a) Additives

The Directorate General SANCO of the European Commission has proposed a new Regulation on food additives[6]. The new Regulation will draw together provisions in the existing Council Directives 94/35/EC on sweeteners for use in foodstuffs[7], 94/36/EC on colours for use in foodstuffs[8] and 95/2/EC on food additives other than colours and sweeteners[8], which lay down the lists of authorised food additives and their conditions of use to the exclusion of all others.

The present project will ***extend the state of the art*** in the assessment of consumer exposure to food additives in the following main areas

- The proposed approach will define a suitable food categorisation system for food additives listed in Directives 94/35/EC, 94/36/EC and 95/2/EC. At present no such standard exists and this allows for subjective error in defining categories (WP 3.1).
- With the help of national database managers, food categories in national databases will be harmonised with the additive food categories (WP 3.1, WP 5).

(b) Flavourings

In the EU, flavouring substances are authorised for use in foodstuffs according to Council Directive 88/388/EEC[10], as completed by Commission Directive 91/71/EEC[11], which sets out the definition of

[5] http://montecarlo.tchpc.tcd.ie/software/; http://www.cremesoftware.com/.

[6] European Commission. Proposal for a Regulation of the European Parliament and of the Council on food additives. COM (2006) 428 final. 2006/0145 (COD) Brussels, 28.7.2006.

[7] European Parliament and of the Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. OJ No.L 237/3, 10.9.1994.

[8] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ No. L 237/13; 10.9.94.

[9] European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ No. L 61/1; 18.3.95.

[10] COUNCIL DIRECTIVE of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (88/388/EEC) (OJ L 184, 15.7.1988, p. 61) available at http://ec.europa.eu/food/fs/sfp/addit_flavor/flav09_en.pdf

flavourings, general rules for their use, requirements for labelling and maximum levels for substances which raise concern for human health legislation. A specific regulation of the European Parliament and of the Council (No 2232/96)[12] lays down a procedure for the establishment of a list of authorised flavouring substances. In application of this Regulation, a register of about 2,700 flavourings used by the food industry in or on foodstuffs in the Member States was adopted. The full database is available at http://ec.europa.eu/food/food/chemicalsafety/flavouring/database/dsp_search.cfm. EFSA is currently evaluating the safety of flavourings by means of a procedure developed by the Joint FAO/WHO Expert Committee on Food Additives and adopted by the Scientific Committee for Food[13]. The final objective is the establishment of a positive list of these substances following a stepwise approach.

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 Scientific Panel on Food Additives, Flavourings, Processing Aids, and Materials in Contact with Food (AFC Panel) of EFSA is currently performing the safety assessment of flavouring substances following this procedure. The reliability of intake estimates on the basis of the default approach based on poundage data (MSDI) is difficult to assess. The EFSA Panel therefore decided to assess dietary exposure to flavourings with two methods: the MSDI and a method based on reported use levels in food (mTAMDI). Exposure assessed with mTAMDI is often up to 100,000 times that calculated using the MSDI; this is, for example, the case for some flavouring substances in FGE18[14]. The EFSA Panel 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.

18 broad food categories may contain flavouring substances.. According to the labelling legislation, the presence of flavouring substance is reported on the label in the list of ingredients[15]. However the name of the substances used are not usually reported. The ingredient list therefore only provides information whether at least one flavour has been added to the product. Current legislation does not provide maximum use levels but indicative concentration levels of flavouring substances can be found in the EFSA opinions published within the procedure for safety evaluation of flavouring substances.

The present project will ***extend the state of the art*** in the assessment of consumer exposure to flavourings in the following areas:

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[11] COMMISSION DIRECTIVE of 16 January 1991 completing Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (91/71/EEC) OJ L 42, 15.2.1991.

[12] REGULATION (EC) No 2232/96 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs. Available at http://ec.europa.eu/food/fs/sfp/addit_flavor/flav04_en.pdf

[13] Scientific Committee on Food. Opinion on a programme for the evaluation of flavouring substances (expressed on 2 December 1999). Available at http://europa.eu.int/comm/food/fs/sc/scf/out45_en.pdf

[14] EFSA (2006) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission related to Flavouring Group Evaluation 18 (FGE.18): Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters from chemical group 6 (Commission Regulation (EC) No 1565/2000 of 18 July 2000) Question n° EFSA-Q-2003-161 Adopted on 1 March 2006. Available at http://www.efsa.europa.eu/en/science/afc/afc_opinions/afc_op_ej330_fge_16.html

[15] European commission (2000) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs OJ L 109, 6.5.2000. Available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2000/l_109/l_10920000506en00290042.pdf

- It will provide DG SANCO with detailed information for about 40 flavouring substances chosen to represent the different typologies of flavours (WP 2.1).
- In particular, food consumption data will be made available with a food categorisation system suitable for assessing potential exposure to flavourings (WP 2.2).
- It will provide the capacity to take into account "high consumption, special groups of consumers and different age groups" as laid out in the call (WP 2.2).
- It will also provide DG SANCO with a tool allowing to efficiently perform exposure assessment on other flavouring substances (WP 2.2, WP 8.1).
- The results of the project will allow a significant reduction in the uncertainty in exposure assessment of flavouring substances which is currently very large (WP 2.2, WP 8.1).

(c) Packaging material migratory compounds

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 including high consumption of foods in particular packaging materials and consumption by potentially vulnerable groups such as infants and the elderly; plus (e) a means to combine this information into reliable estimates of exposure.

Furthermore, estimating consumer exposure to substances migrating from food contact materials is only one part of the risk assessment / risk management process. 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. Food additives always have ADI values (acceptable daily intake values) and flavouring substances have exposure thresholds based on Cramer Classes - a type of structure-activity relationship. But for evaluating the toxicity potential of substances migrating from food contact materials only classical toxicology approaches are used in Europe presently. These are too slow, costly, and involve animal studies. They are not sustainable for the thousands of chemicals needed to make food packaging materials - particularly the components of the so-called 'forest of peaks'.

The present project will ***extend the state of the art*** in the assessment of consumer exposure to food packaging migratory material in the following areas:

- FACET will create a database of the chemicals that are likely to be contained in different packaging materials used across Europe (WP 4.1.1, 4.1.2, 4.1.5).
- With the help of a consortium of industry partners, a comprehensive European database on food packaging usage patterns will be established for the first time (WP 4.1.3, 4.1.4).

- FACET will develop a new, 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 (WP 4.2.1).
- FACET will conduct migration research to derive fundamental partition and diffusion parameters that describe the migration process for packaged foods (WP 4.2.2, 4.2.3).
- FACET will develop 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 (WP 4.2.4, 4.2.5).
- A new *in silico* QSAR approach will be developed, validated and used to evaluate the toxicological significance of exposure to packaging substances (WP 4.3).

(d) *Food chemical occurrence data*

If a chemical or additive is permitted for use in a given foodstuff, it does not necessarily follow that the chemical will be present[16]. 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.[17].Only a few food ingredient databases are currently in existence in the E.U. These food ingredient databases investigate nutrients, ingredients, additives and packaging material in contact with the foods.

It should be noted that an ingredient database is never going to be truly representative of an entire food supply. Changes in ingredient formulations, introduction of new products, deletion of old products and regional variation of certain products all contribute to a dynamic food market.

The present project will ***extend 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 (WP5, WP6)
- Establishing a protocol for populating such a database (WP6)
- Creating a new database with data from 8 partner countries (Ireland, UK, France, Italy, Finland, Poland, Hungary and Portugal) (WP6)

(e) Food chemical concentration data

Obtaining data on the concentrations of chemicals in foods is a major difficulty in estimating exposure to food chemical intake. In the case of food additives a list exists in EU law as to the maximum levels of a given food additive which can be used in a food. 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. Data from targeted chemical analysis exists but these are *ad hoc* and sporadic. The present study is very fortunate in having CIAA, the EU's largest food industry grouping as a partner who will work with the CIAA industry panels to create a sustainable database on food additive concentrations in target foods. These data will be technological use levels and where the data is from brands, the source will be

[16] Lowik, M.R.H., 1996, Possible use of food consumption surveys to estimate exposure to additives. *Food Additives and Contaminants*, **13**, 427 – 441.
[17] Nutriscan, 1994, Options for the routine collection of usage levels of food additives in the European Union. Final Report (Dublin: Nutriscan Ltd.)

anonymised. Data on flavouring concentrations will be obtained from an exercise that EFSA has begun on flavourings and packaging material concentrations will be based on advanced migratory studies.

The present project will ***extend 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 (WP 9).
- Creating a database on patterns of usage of different flavourings and blends of flavouring compounds (WP 2.1).
- FACET will establish 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 (WP 4.1).

(f) Food intake data

Of all the datasets needed for estimating exposure to food chemical intake, the most abundant by far are food consumption databases. Many of the EU states 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 and getting countries to abandon one method for another is difficult given the need to monitor trends and given that methodologies may influence distribution about the mean. 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. The simple example is data on intakes of "sea food", to "shell fish" and "fish" and from "fish" to "fatty fish" or "white fish" and from "fatty fish" to "grilled" or "poached" salmon. This variation in detail can occur at the point of data collection or at the point of data entry into established database architecture. Any attempt to create a "harmonised database" as set out in the call, can only happen if the task has very specific questions to the national database managers and that is the case in the present project. When target chemicals are identified, target food categories will be established and it is these target food categories which will form the harmonised food intake database. 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 latter databases will be used to establish a set of rules on the use of data such as means and standard deviations to establish predicted high end consumers and also a set of rules will be established for the separate use of data on data from "consumers only" versus the total population which would include non-consumers of the target foods.

The present project will ***extend the state of the art*** in extending knowledge of food intake data by

- Agreeing a new tiered and harmonised food intake database structure (WP 5)
- Populating that database with targeted food intake data from all member states (WP 5)
- Setting out a series of rules on the use of datasets to project to high end consumers and to ensure that all vulnerable groups are included (WP 5 & 7.1)

(g) Regional modeling

The risk management of chemicals in food (additives, flavours, packaging material migrants, etc.) requires knowledge about the amounts of food containing those chemicals that are consumed. Effective risk management requires more than simple population averages because this does not take into account differences between individual food consumption patterns. Certain individuals habitually

consume more of certain kinds of foods than others and these people must be taken into account in the risk equation. Peoples' patterns of food consumption vary according to many factors. Age is particularly important because children have considerably higher energy requirements and thus food consumption than adults on a body weight basis and it is necessary to express intakes on a bodyweight basis to make realistic comparisons with safety standards such as the ADI. 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. Food consumption data exist for many countries but they frequently represent only population averages and no detailed information about inter-individual variation or different age groups is available. 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, although not necessarily in a conventional data base format. For example, 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 will ***extend the state of the art*** in the development of regional models as follows:

- FACET will develop a novel modeling approach to generate surrogate data to represent missing national dietary patterns (WP 7.1).
- Bayesian analysis and formal elicitation of expert opinion will be used to refine intake models and a targeted food frequency questionnaire will provide quantitative validation (WP 7.2).

(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. These calculations are typically performed using simple tools such as Microsoft Excel. 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 (www.cremesoftware.com), the MCRA model (RIKILT) and the CSL model. These tools have allowed uncertainty and variability to be quantified in more detailed exposure assessments.

Issues with the current state of the art include the following. Although current deterministic methods are thought to be conservative – or perhaps over-conservative – their true relation to actual intakes has not been established. Therefore it is not known whether they provide an appropriate level of protection for consumers. The existing probabilistic models require data from detailed food consumption surveys.

They are thus restricted to the minority of EU member states where which such data exist, and their benefits cannot be realised for EU-level assessments. The existing probabilistic models quantify only a few of the uncertainties affecting dietary intakes, typically only sampling uncertainty for consumption and concentrations. Consequently, confidence intervals produced by these models represent only part of the overall uncertainty.

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.

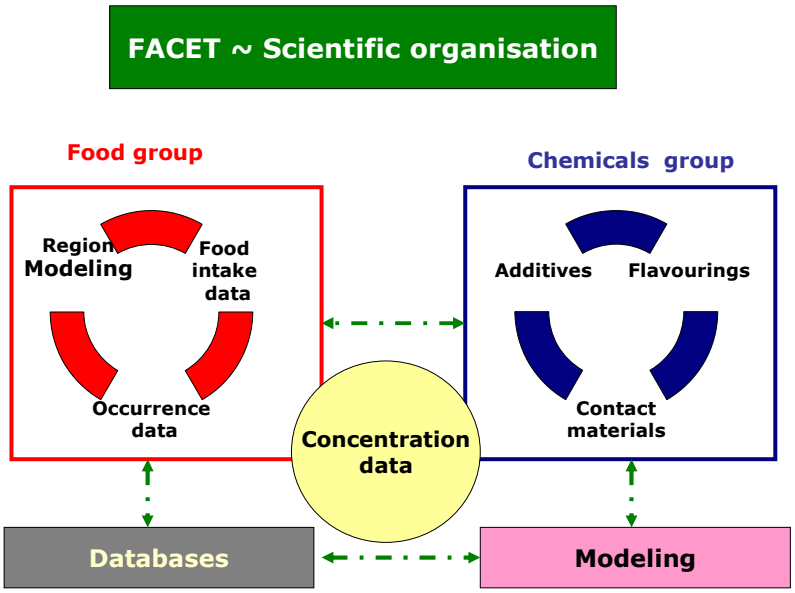
The present project will ***extend the state of the art*** in the development of food chemical exposure models as follows:

- FACET will provide for the first time a validated software programme for deterministic and probabilistic modeling of food chemical intake (WP 8)
- FACET will quantify variability and uncertainty in the probabilistic modeling of food chemical intake and propagate the model with confidence intervals for estimated intakes (WP 8).

B.1.3 S/T methodology and associated workplan

B.1.3.1 Overall strategy and general description

The diagram below outlines the overall strategy of the workplan which can be described in four distinct areas all of which are inter-dependent on one another.



There are 8 research workpackages and also one management and one dissemination workpackage.

- *The Chemicals group (Flavourings, Additives, Packaging Materials and Concentrations workpackages)*

This group will have as its focus, the target chemical type as outlined in the call. Each will seek to determine a list of target chemicals in their given area and will then seek to ascertain relevant concentration data. These data will be gathered independent of the group responsible for collecting occurrence data since both are different. The concentration data will refer to what levels of target chemicals would be present if these target chemicals were used and the occurrence group is responsible for finding information out on the latter. In addition to concentration data, this group will propose a list of foods likely to contain the target chemicals and in that regard will interact with the "Foods group"

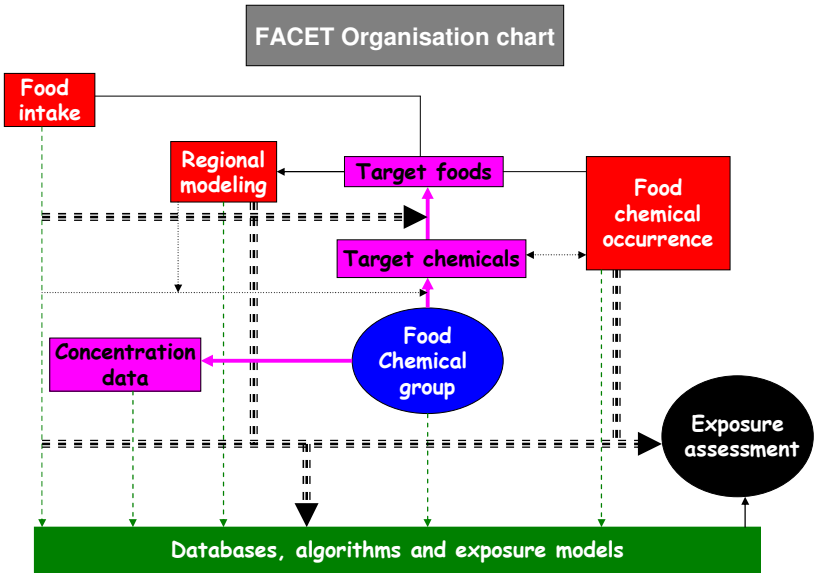
- *The Foods group (Food intake, Chemical occurrence and Regional modeling workpackages)*

This group will operate together for several parts of their workpackage. They will form a link with EU member states. The food intake group will link with the chemicals group to agree definitions of food groups in order to estimate intakes of such defined food groups and will work with the Food intake database group to create a suitable database architecture for food intake data. This group will work closely with the Regional Modeling Group to create the necessary input into the regional models. The occurrence group will work to procure food chemical occurrence data and the food chemical occurrence surveillance programme will work closely with the food chemicals group.

- *The Database and Modelling groups (Exposure modeling workpackage)*

Databases will need to be constructed which have connectivity between intake, occurrence and concentration for each chemical. These databases will exist in tiers corresponding to the complexity of the data. The modeling group will include those involved in the packaging food chemical group in modeling migration of food contact materials into food. It will also involve almost all workpackages in agreeing algorithms for probabilistic modeling for exposure and the software development and validation will be the responsibility of WP 8.

A graphic representation of the components showing their interdependence:
The generation of the list of food chemicals is at the heart of the project and will be subject to some input by all partners (lightly dashed lines). As this is happening, the three workpackages associated with the food intake and food chemical occurrence end (Work-packages 5, 6 and 7) will be in dialogue with the member states and a preliminary position on possibilities for food group classification will be developed. When the time comes for food chemicals to be aligned with food groups, these three workpackages will have a major input into that decision (double dashed black lines). These work-packages will then work with the member states to acquire the tiered food intake data and the targeted food ingredient data (grey lines). The food chemical group (Work-packages 2, 3, 4 & 9) will begin the task of gathering food chemical concentration data and all workpackages will feed data into the databases (light dashed green arrows). Work-packages 7 and 8 will specifically deal with database design, exposure algorithm development and exposure model development. However these tasks will also require input from all Work-packages in the project and all work-packages will also have major input into the analysis and interpretation of the exposure assessment.



B.1.3.2 Timing of the work packages and their components
Refer to Gantt chart on the next page:

Gantt Chart: FACET

WP	Details	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
		Year 1												**Year 2**												**Year 3**												**Year 4**											
1	**Project Management**																																																
	Deliverables									1.1, 1.2																																							
	Milestones																																																
2	**Flavourings**																																																
	Deliverables												2.2																		2.1, 2.3																		
	Milestones												4, 5			9			12						17												23												
3	**Additives**																																																
	Deliverables									3.1									3.2																		3.4												
	Milestones						2						4, 6			9									15, 17												23												
4	**Packaging**																																																
4.1	**Packaging composition & usage**																																																
	Deliverables																														4.1.1						4.1.2												4.1.3
	Milestones						1						4			9			13						16, 17												23												
4.2	**Tools to establish migrant concentrations**																																																
	Deliverables																																								4.2.1				4.2.2				
	Milestones																												19				21																
4.3	**Use of QSAR modelling**																																																
	Deliverables																																4.3.1																
	Milestones															11																																	
5	**Food intake database**																																																
	Deliverables																																				5.1, 5.2						5.3						
	Milestones												4, 7			9			14						17, 18												22												
6	**Food Chemical Occurrence Database**																																																
	Deliverables																																				6.1												
	Milestones												4			9, 10																					23												
7	**Regional Dietary Modelling**																																																
	Deliverables																														7.1												7.2.1						7.2.2
	Milestones												7												18						20										25		26						
8	**Development, validation dietary models**																																																
8.1	**Model design & validation, algorithm development**																																																
	Deliverables																																8.1.1										8.1.2						8.1.3
	Milestones																																																
8.2	**Online database manager**																																																
	Deliverables																																																8.2.1
	Milestones									3																																							27
9	**Concentration Data**																																																	
	Deliverables																																				9.1												
	Milestones						2						6, 8												15												24												
10	**Dissemination**																																																
	Deliverables					10.1				10.2																																	10.3						10.4
	Milestones																																																28

Deliverable numbers are highlighted in green (refer to page 23), Milestone numbers are highlighted in yellow (refer to page 53)

B.1.3.3 Work package list / overview

Work package list

Work package No	Work package title	Type of activity[4]	Lead beneficiary No	Person-months	Start month	End month
1	Project management	MGT	1	40	1	48
2	Flavourings	RTD	7	95	1	48
3	Additives	RTD	6	76	1	48
4	Packaging	RTD	3	283	1	48
5	Food intake	RTD	2	72.6	1	48
6	Chemical occurrence	RTD	1	112.6	1	48
7	Regional modelling	RTD	5	115.6	1	48
8	Databases and modelling	RTD	15	126.6	1	48
9	Concentration data	RTD	19	18	1	48
10	Dissemination	OTHER	1	21	1	48
	TOTAL			961.4		

B.1.3.4 Deliverables list

List of Deliverables

Del. no.	Deliverable name	WP no.	Lead beneficiary	*Estimated indicative person-months*	Nature[5]	Dissemination level	Delivery date (proj. month)
1.1	Copies of all ethical approval letters from all partners	1	1	1 month	R	PP	9
1.2	Short report to Commission on initial progress of project	1	1	0.5 month	R	PP	9
2.1	A report including a database of reported concentration levels of target flavouring substances in food and the assessment of uncertainty of occurrence	2	7	16 months	R	PU	30

[4] Insert one of the following 'types of activities' per WP (only if applicable for the chosen funding scheme – must correspond to the GPF Forms):
RTD = Research and technological development including scientific coordination applicable for collaborative projects and NoEs
DEM = Demonstration - applicable for collaborative projects
OTHER = Other activities (including management) applicable for collaborative projects, NoEs, and CSA
MGT = Management of the consortium - applicable for all funding schemes
COORD = Coordination activities – applicable only for CAs
SUPP = Support activities – applicable only for SAs

[5] Please indicate the nature of the deliverable using one of the following codes:
R = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

	and concentration data based on analytical data						
2.2	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.	2	7	12 months	R	PU	12
2.3	A guidance document for the development of models of dietary exposure to flavouring substances.	2	7	12 months	R	PU	30
3.1	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	3	6	12 months	R	PU	9
3.2	List of high priority food additives for the collection of use levels	3	6	9 months	R	PU	18
3.4	Report on exposure assessment methodology for food additives	3	6	27 months	R	PU	36
4.1.1	List of substances used in packaging materials for foodstuffs and a list of foodstuffs which are packaged in those materials	4	3	10.5 months	R	PU	30
4.1.2	Report on verification of D4.1.1 (list based on market surveys)	4	3	14 months	R	PU	36
4.1.3	Report on testing the database for estimating exposure to a number of test substances (aim 10 per sector group)	4	3	22 months	R	PU	48
4.2.1	Migration model to calculate concentration data in foodstuffs, with verification for selected substances (aim 10 per sector group) for use in exposure model	4	10	55.5 months	R	PU	40
4.2.2	Probabilistic migration model into foodstuffs, with experimental verification, for multi-layer/multi-material FCM	4	10	54 months	O	PU	44
4.3	Report on verification of QSAR approach for migrants from food packaging materials.	4	3	21 months	R	PU	32
5.1	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.	5	2	18 months	O	PU	36
5.2	Guidelines for the appropriate use of the harmonized database	5	2	6 months	R	PU	36
5.3	A report on the value of targeted ancillary food frequency questionnaires for the estimation of food chemical intake	5	2	6 months	R	PU	42
6.1	A harmonised database on targeted food chemical occurrence in 8 member states	6	1	18 months	O	PU	36
7.1	European model for extrapolation of national food consumption patterns	7	5	94.5 months	R	PU	30
7.2.1	Database of national food consumption	7	5	15 months	R	PU	42

7.2.2	WP7 Validation report on the database of national food consumption	7	5	2 months	R	PU	48
8.1.1	Draft exposure assessment software tool for external evaluation	8	15	49.5 months	O	PU	32
8.1.2	Final exposure assessment software tool, PC based and publicly available	8	15	16 months	O	PU	42
8.1.3	Model Validation Report	8	15	25.5 months	R	PU	48
8.2.1	Exposure Analysis Report	8	15	16 months	R	PU	48
9.1	Database on the technological use and ranges of food additives selected for study within the FACET project	9	19	18 months	O	PU	36
10.1	Establishment of the project website	10	1	3 months	O	PU	5
10.2	Produce a logo for the project and flyers to communicate information about the project	10	1	4 months	R	PU	9
10.3	Training manual for Software	10	15	4 months	O	PU	42
10.4	Final plan for dissemination	10	1	2 months	O	PU	48
			TOTAL	574 months			

B.1.3.5 Work package descriptions

Work Package Number	**1**	**Start date or starting event**					Month 1
WP Title	Project management						
Activity Type	MGT						
Participant Number	1						
Participant Short Name	UCD						
Person-months per participant	40						

Objectives
1. To develop and sustain effective technical coordination and project management to successfully complete all aspects of the project, in accordance with the EC grant agreement

Description of work
The management workpackage will entail administration of communication within WPs, the organisation of meetings, the preparation of technical and non-technical reports and the completion of all financial obligations. The main areas of activity of the coordinator (Partner 1) will be to:

Task 1: To manage the organisational structures of FACET. This will include supporting the project Management Groups, the project Plenary Group and those relating to the member states, coordinating a consortium agreement which is acceptable to all partners, overseeing the distribution of funds to consortium members, coordination of all audit certificates organising and participating in all project scheduled meetings, managing any issues in relation to IPR, as defined in the IPR agreement and making key decisions on the progress and direction of the project.
Task 2. Obtain ethical approval letters from relevant partners.
Task 3. To oversee reporting to the Commission. This will include coordinating the preparation and submission of scientific and financial progress reports to the Commission and compilation and submission of the project accounts to the commission.

No.	**Deliverable**	**Month**
1.1	Copies of all ethical approval letters from all partners	9
1.2	Short report to Commission on initial progress of project	9

Work Package Number	**2.1**	**Start date or starting event**					Month 1
WP Title	Selection of representative flavouring substances, development of the flavouring substances concentration database and assessment of uncertainty in these data						
Activity Type	RTD						
Participant Number	7	8					
Participant Short Name	INRAN	TUM					
Person-months per participant	34	23					

Objective
To develop a database of concentration levels for a set of flavouring substances that represent the 2,700 currently on the market

Description of work
Task 1: For each of the approximately 2700 flavouring substances currently on the market, information will be collected with respect to the toxicity (TTC class), the estimated dietary exposure (mTAMDI where available), the reported volume of production and the reported distribution among food categories. These data will be retrieved from the evaluation opinions released by the competent authorities such as the Council of Europe, the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). On the basis of the information compiled, the flavouring substances will be assigned to homogeneous categories according to (i) margin between TTC class and estimated dietary exposure, (ii) patterns of use (type of food products, concentration levels, etc.), (iii) sensory characteristics, and (iv) natural occurrence in foods at significant concentration levels. Partner 8 will lead this task and will receive support from Partner 7.
Task 2: Representative flavouring substances (target flavourings) will be selected out of each of the above mentioned categories in order to represent the conditions related to the current methodological difficulties in the assessment of exposure of this specific category of chemicals. Considering that the potential dietary exposure to flavourings expressed per kg body weight is higher in children, priority in the selection process will be given to those flavouring substances present in foods and beverages particularly consumed by children. Partner 8 will lead this task and will receive support from Partner 7.
Task 3: A database of reported concentration levels of the target flavourings in foods will be developed. The database will be organized according to food descriptors that are compatible with the food descriptors of food consumption data. The database will be filled by making use of all available sources of reported concentration levels of flavourings in food. The main source of data will be (i) the use levels reported for the flavouring substances previously evaluated by the Council of Europe or by the Scientific Committee for Food (n = 46) (ii) the use levels provided by the European Flavour and Fragrance Association (EFFA) for the flavouring substances currently being evaluated by EFSA (n = 1300), (iii) the use levels currently being retrieved by the International Organization of the Flavor Industry (IOFI) following a specific call for data by JECFA on some flavouring agents in the low and in the high poundage area (n = 55) and (iv) the use levels currently being retrieved by EFFA following a specific request by DG SANCO on the substances evaluated by JECFA and classified in structural class III (n = 141). These data will be complemented with data from the literature, where available. Partner 7 will be responsible for this task and will receive support from Partner 8.
Task 4: Assessment of the uncertainty of occurrence and concentration data. The uncertainty of occurrence data, collected within the *ad hoc* survey performed within WP6, and of the reported concentration data retrieved in Task 3 of WP2 will be assessed through analytical

determinations in products available on the market. Overall, approximately 1000 quantitative analyses will be performed to create data sets for flavouring substances selected. Food matrices will be selected to cover representative uses of the flavouring substances; special emphasis will be on flavouring substances present in foods and beverages particularly consumed by children. The issue of volatility and possible losses during storage will be considered. Partner 8 will be responsible for this task; a number of analytical determinations will be performed by Partner 7.

No.	Deliverable	Month
2.1	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	30

Work Package Number	2.2	Start date or starting event		Month 1			
WP Title	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.						
Activity Type	RTD						
Participant Number	7	8	1	2			
Participant Short Name	INRAN	TUM	UCD	UU			
Person-months per participant	31	5	1	1			

Objectives

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.

Description of work

Task 1: In collaboration with WP6, the food products and categories to be included in the "Occurrence survey" will be selected in order make possible the collection of information related to the presence of flavouring substances in processed foods. Two important pieces of information that can be retrieved from the labels of processed foods are: 1) the absence of any flavouring substance (if the word "flavour" does not appear in the ingredient list) and 2) the taste of a product (if present in the name of the product i.e. liquorice flavour, chocolate flavour, etc). Special attention will be given to "character impact compounds" i.e. to those flavouring substances that impart a specific odour that can be easily recognized. Partner 7 will be responsible for this task with support from Partner 8 and Partner 1.

Task 2: A categorization system for food products will be developed so that the information collected within food consumption surveys in the eight EU Member States involved in WP5 can be used for the assessment of exposure to flavouring substances. Instructions will be provided in terms of food coding, recipe break up, etc. in order to support the Member States in categorizing food consumption information according to the above mentioned system. Partner 7 will be responsible for this task.

Task 3: Guidance to the development of exposure models to flavouring substances will be provided to WP8. The models will make it possible to assess potential exposure to the selected flavouring substances for all the Member States that will make available data in

terms of food consumption categorized according to the system developed for flavouring substances in Task 2. Special consideration will be given to the dietary exposure of high consumers of foods and beverages susceptible to contain flavouring substances at relatively high concentration levels. The exposure models should allow realistic estimates of long term dietary exposure to flavouring substances in such consumers. The impact of consumers' flavour loyalty (among products and within products) will therefore be considered to estimate high levels of dietary exposure. The possibility to use retailer's data (collected by means of fidelity cards) and/or purchase data (collected by market share companies) to quantify loyalty to flavours will be investigated. On the other hand, the potential overestimate related to the short duration of food consumption surveys will also be taken into account. Partner 7 will be responsible for this task.

No.	Deliverables	Month
2.2	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.	12
2.3	A guidance document for the development of models of dietary exposure to flavouring substances.	30

Work Package Number	**3.1**	**Start date or starting event**					Month 1
WP Title	Food Additives codification						
Activity Type	RTD						
Participant Number	6	5	19	1			
Participant Short Name	AFSSA	FCRA	CIAA	UCD			
Person-months per participant	12	2	1	1			

Objectives
1. To propose a methodology for the codification of the national dietary surveys appropriate for EU exposure assessment to foods additives

Description of work
(AFSSA will lead these tasks, with support from Partners 1, 5 and 19)
Task 1: Constitution of a list of food categories existing in food additives directive (94/35/EC, 94/36/EC and 95/2/EC) and in the General Standards for Food Additives (GSFA) of the Codex Alimentarius CCFAC. Particular attention will be given to the consequences on food classification of the DG SANCO proposal of a new regulation on food additives.
Task 2: Among the existing food categories, difficulties to interpret their content and limits will be identified by interviewing different users of these categories: risk and exposure assessors, national authorities, industry members.
Task 3: With the help of DG SANCO and national authorities each food category will be described with examples of foods included and excluded.
Task 4: According to the precision of the description of food categories, criteria for the selection of dietary surveys available for exposure assessment to food additives will be defined. The different national dietary surveys available in Europe for the FACET project will be evaluated according to these criteria.
Task 5: For the selected dietary surveys, procedures will be defined to allocate the food items of the dietary surveys to the different food categories useful for food additives monitoring and exposure assessment. Recommendations will also be provided on the management of food products and their ingredients in the dietary surveys: for example, what is the right level of decomposition of composite foods in ingredients?

No.	**Deliverable**	**Month**
3.1	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	9

Work Package Number	**3.2**	**Start date or starting event**					Month 9
WP Title	Food additives prioritization						
Activity Type	RTD						
Participant Number	6	19	5	1	2		
Participant Short Name	AFSSA	CIAA	FCRA	UCD	UU		
Person-months per participant	9	3	2	1	1		

Objectives
1. Selection of high priority food additives to be studied for exposure assessment
2. Preparation of the sub-workpackages on levels of food additives in foods

Description of work
Task 1: The occurrence WP (WP6) will not need a prioritization of food additives because all occurrence information for food additives will be recorded for the foods collected. WP6 will provide useful information to prioritize food additives levels to be surveyed: frequency of use by additive and food category (Partners 1, 5 and 6).
Task 2: Other sources of information will be used to prioritize food additives for use level collection: results of EU monitoring described in the « Report from the commission on dietary food additive intake in European Union, 01 October 2001 ». For recent EU countries, the combination of maximum use levels and national dietary survey reports or DAFNE or WHO GEMS FOOD consumption data compared to ADIs will provide priorities. Also, scientific publications, review of EFSA and national authorities' reports and advice and the Nordic report will provide additional information (Partner 6).
Task 3: Industry will be contacted to provide, if available, production levels (Partner 19).

No.	Deliverable	Month
3.2	List of high priority food additives for the collection of use levels	18

Work Package Number	3.3	Start date or starting event					Month 18
WP Title	Food additives use level collection						
Activity Type	RTD						
Participant Number	19	6					
Participant Short Name	CIAA	AFSSA					
Person-months per participant	12	15					

Objectives
1. To collect information on real usage levels for the high priority food additives defined previously

Description of work:
Task 1: Elaboration of a questionnaire on usage levels to be sent to industry members, according to priority food additives and food categories (Partners 6 and 19).
Task 2: Compilation of a list of industry members as a sampling frame for the survey on usage levels. From this list in different EU countries, a sample of enterprises will be randomly selected with a stratification according to the size of the enterprise. The sampling rate will be different between international groups (exhaustive) and SMEs (Partner 19).
Task 3: A small pilot study will allow checking and eventually improving the questionnaire. Questionnaires will be sent and recalls will be organized to increase the response rate (Partner 19). The answers of the industry participants to the survey will be analysed and statistics on use levels will be provided (Partner 6).
Task 4: On the same time, a consultation of food technology experts will be organised about the usual ranges of use levels (Partner 6). The food additives and food categories with a too low response rate will be identified for future research. Survey results on use level will be compared with available information from scientific publications when available for the most frequently studied food additives.

Work Package Number	**3.4**	**Start date or starting event**		Month 24		
WP Title	Food additives exposure assessment methodology and additional sources of information					
Activity Type	RTD					
Participant Number	6	5	1	15		
Participant Short Name	AFSSA	FCRA	UCD	Creme		
Person-months per participant	12	2	1	2		

Objective

1. Guidance to exposure assessment and to the development of dietary surveys to take into account the necessary information for food additives intake surveillance

Description of work

This sub-work package will bring together the different information provided by the previous steps to prepare the exposure assessment to food additives.

Task 1: The parameters of deterministic and probabilistic approaches will be discussed; additional information available in dietary surveys will be identified like the brand and name of the products, the claims like "light" for intense sweeteners intake assessment (Partners 6 and 15).

Task 2: Because of the shortness of dietary survey duration and in order to be able to take into account the brand loyalty parameters, other sources of information on consumption frequencies like marketing panels or propensity/food frequency questionnaires will be identified and tested for at least one country. Ongoing research on reduction of intra-individual day-to-day variance of food intake will provide recommendations on exposure assessment methodology (Partners 1, 5 and 6).

Task 3: The specifications for food additives exposure assessment and datasets of occurrence and levels of use will be transmitted to the FACET exposure assessment work package (Partner 6).

No.	**Deliverable**	**Month**
3.4	Report on exposure assessment methodology for food additives	36

Work Package Number	**4.1**	**Start date or starting event**		Month 1			
WP Title	Packaging composition and usage						
Activity Type	RTD						
Participant Number	03 (WPL)	04	12	21			
Participant Short Name	CSL	CEPE	STFI.PF	JRC			
Person-months per participant	16	44	31	4			

Objective
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 (WP4.2) to be assigned to food consumption data (WP5) using the tools developed (WP8)

WP4.1 is divided into 5 separate sub-Work Packages: 4.1.1 to 4.1.5:

No.	**Deliverables**	**Month**
4.1.1	List of substances used in packaging materials for foodstuffs and a list of foodstuffs which are packaged in those materials	30
4.1.2	Report on verification of D4.1.1(list based on market surveys)	36
4.1.3	Report on testing the database for estimating exposure to a number of test substances (aim 10 per sector group)	48

Sub-Work Package Number	**4.1.1**	**Start date or starting event**		Month 1			
WP Title	Compiling an inventory list of substances used to make food packaging materials						
Activity Type	RTD						
Participant Number	03	04	12	21			
Participant Short Name	CSL	CEPE	STFI.PF	JRC.			
Person-months per participant	1	6	2	1			

Overall task of sub WP. To obtain information on the chemical substances used to make different food packaging materials

Description of work
Sub-task 1. P04 will compile an inventory list of substances used in food packaging materials. It will be in two parts. First, a complete list of substances used in the direct food contact layer. Second, a list of substances not intended for food contact but known to be used in other layers in inks and adhesives, using publicly available information. The task will be broken into industry sectors; (a) plastics – rigid; (b) plastics – flexible; (c) metal – coated; (d) metal – uncoated; (e) paper and board; (f) laminated paper and board and other relevant sectors which are in the process of joining the industry consortium.

Sub-task 2. Information will be collected to assist WP4.2. This will include CAS no., molecular weight, molecular formula, $\log P_{OW}$ and other physico-chemical parameters of potential impact in predicting migratory behaviour.

Sub-task 3. P12 advised by P03 and P04 will develop a database for this information. The final consolidated inventory list of food packaging substances could also form the basis for an updated DG-SANCO Synoptic Document.

Sub-Work Package Number	**4.1.2**	**Start date or starting event**		Month 3			
WP Title	Occurrence and concentration data for substances in packaging materials						
Activity Type	RTD						
Participant Number	03	04	12	21			
Participant Short Name	CSL	CEPE	STFI.PF	JRC			
Person-months per participant	3	6	5	-			

Overall task of sub-WP. To link substances with those packaging materials in which they could be present, along with concentration data in the packaging that will allow estimates of migration to be made.

Description of work

Sub-task 1. P04 will link substances in the inventory list with those packaging materials in which they could possibly be present. In some cases it will be clear-cut. However in the majority of cases a probability will be assigned e.g. polythene has a 40% +/- 20% chance of containing antioxidant X.

Sub-task 2. This information will then be amplified to include estimates of the concentrations of substances likely to be found in the different categories of packaging materials. This will use literature sources and unpublished (but documented and traceable) company reports. In the absence of data, estimates will be based on technological considerations.

Sub-task 3. P12 will incorporate this information into the substance database.

Sub-Work Package Number	**4.1.3**	**Start date or starting event**		Month 3			
WP Title	Listing different foodstuffs with the packaging materials that are used for them						
Activity Type	RTD						
Participant Number	03	04	12	21			
Participant Short Name	CSL	CEPE	STFI.PF	JRC			
Person-months per participant	3	15	4	-			

Overall task of sub-WP. 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.

Description of work

Sub-task 1. Data from recent packaging usage surveys (IRE for children; UK for infants and the elderly; NL for the general population etc) will be combined with data from on-going industry-sponsored projects (e.g. Matrix and CEFIC-FCA). The different market shares for different types of packaging for defined categories of foodstuffs will be estimated. This WP entails close co-operation with WP 5 because food coding that reflects the packaging of the foodstuffs will need to be developed.

Sub-task 2. The surface area to volume ratios will be estimated for different types of packaging and different foodstuffs. This will be for a few selected foodstuffs and types of packaging, due to the complexity and lack of detailed market surveys.

Sub-task 3. The links made between food items, food groups and/or food categories, and the packaging materials used for them, will be incorporated into a database.

Sub-Work Package Number	**4.1.4**	**Start date or starting event**				Month 1
WP Title	Linking packaging materials and their substances with different foodstuffs and concentration data					
Activity Type	RTD					
Participant Number	03	04	12	21		
Participant Short Name	CSL	CEPE	STFI.PF	JRC		
Person-months per participant	3	12	2	-		

Overall task of sub-WP. To link foodstuffs consumed with the concentration of migrants originating from their packaging.

Description of work

Sub-task 1. The foodstuffs, their packaging, the occurrence or not of a particular substance in the packaging, migration levels into foods, food simulants or from mathematical modelling (ex. WP4.2) will be combined with market shares, surface to volume ratios and other relevant data in order that a database(s) can be populated with the required information with the links needed.

Sub-task 2. Statistical modelling will be used from WP7 working with WP4.1.5, in order to cover data gaps and give an estimate of uncertainty bounds. Results feed into WP4.1.5.

Task 3. Using the exposure modelling tools developed in WP8 an estimation of consumer exposure to test substances will be run, selecting 10 substances for all packaging sectors (Pl, Me, Pa, see WP4.1.1).

Sub-task 4. The project Stakeholder Group will critique the exposure estimates and the supporting evidence for the 30 test substances. They will recommend any more efficient or transparent ways to populate the databases, fill the data gaps, and estimate exposure. These recommendations will be implemented.

Sub-Work Package Number	**4.1.5**	**Start date or starting event**				Month 6
WP Title	Extending the databases to represent all EU member states					
Activity Type	RTD					
Participant Number	03	04	12	21		
Participant Short Name	CSL	CEPE	STFI.PF	JRC		
Person-months per participant	6	5	18	3		

Overall task of sub-WP. To ensure that all EU Member States are represented and to establish the know-how to fill data gaps on packaging use.

Description of work

Sub-task 1. The STFI packaging database for Sweden (1999-2006) will be extended to cover four additional countries, representative of different European regions - Mediterranean (Italy), Atlantic (UK), Baltic (Estonia) and Central European (Poland).

Sub-task 2. Selection of 100 market-leading food products in the five countries. Classification of food type according to Directive 85/572/EEC. Identification of each layer of packaging materials using a classification system provided by P04.

Sub-task 3. The reclassification of foods within WP4.2 will influence the migration data that are associated with different food groups. The impact of this on exposure estimates will be assessed by considering how the links between packaging type/composition and food item/group classification will change.

Sub-task 4. For the 100 market leaders in 5 countries, will record the total (a) food contact area (m^2); (b) packaging weight (kg); (c) food weight (kg); (d) number of each item sold. This will be categorised for all the different packaging materials, layer by layer, such as plastics, coatings, inks, paper and board.

Sub-task 5. Collection of 3,000 food packages from at least 8 countries in cooperation with WP6. The collectors will record the basic food/packaging details (food item description, food weight, contact area, storage conditions, etc). The food contact layer of the packaging will be identified by P12 using FTIR. P04 and 21 will conduct chemical analysis (GC-MS and LC-MS) on composites, to compare with the compositional details recorded in WP4.1.2. This will provide a check on how homogeneous or heterogeneous is the packaging use and packaging composition across the Member States.

Sub-task 6. The ten most common food contact layers in the EU for the food groups according to classification in 85/572/EEC and the new classification system proposed in this project will be identified. This will influence the selection of packaging materials and substances that will be modelled in WP4.2 as test cases.

Work Package Number	**4.2**	**Start date or starting event**				**Month 1**
WP Title	Development of tools to establish concentrations of migrants from packaging materials in foods					
Activity Type	RTD					
Participant Number	03	04	09	10 (WPL)	16	18	21
Participant Short Name	CSL	CEPE	FABES	Fraunhofer	USC	INCDTIM	JRC
Person-months per participant	18	3	13	50	40	18	25

Objective

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. The model will be developed further in order to predict migration from all relevant packaging sectors covered by this project.

Description of work

WP Overview. Exposure modelling needs concentration levels. Full analytical determination and market surveys are impossible. Migration into food follows well known physical laws and migration modelling is a promising way to get these concentration levels. Migration modelling is based on two major factors: (i) the kinetic factor is the diffusion constant of a migrant in the plastic(s) whose diffusion is considered to be the rate limiting step, and (ii) the thermodynamic factor is the partition coefficient of a migrant between the food contact plastic and the food simulant $K_{P/F}$. Where (a) more precise and realistic modelling is needed (as necessary for exposure assessment) and (b) foods themselves are the contact matrix and not simple food simulating liquids, then migration modelling is not yet advanced enough due to a lack of physico-chemical data and scientific understanding.

These scientific gaps and deficiencies will be tackled by 5 modular sub-WPs.

No.	**Deliverables**	**Month**
4.2.1	Migration model to calculate concentration data in foodstuffs, with verification for selected substances (aim 10 per sector group) for use in exposure model	40
4.2.2	Probabilistic migration model into foodstuffs, with experimental verification, for multi-layer/multi-material FCM	44

Sub-Work Package Number	**4.2.1**	**Start date or starting event**			Month 1	
WP Title	New thermodynamic classification of foods/food groups based on solubility properties (log $P_{O/W}$ versus $K_{P/F}$ studies)					
Activity Type	RTD					
Participant Number	03	04	09	10 (WPL)	16	21	
Participant Short Name	CSL	CEPE	FABES	Fraunhofer	USC	JRC	
Person-months per participant	7	1	0.5	33	5	10	

Overall task of sub-WP. (a) To establish for migrants and foods/foodgroups correlations between log$P_{O/W}$ (octanol-water partition coefficient) and partition coefficient $K_{P/F}$ in contact with non-polar, medium polar and polar food contact plastics layers. (b) To explore the temperature dependency of log$P_{O/W}$ and $K_{P/F}$ of migrants and the validity of log$P_{O/W}$ values obtained by calculation.

Description of work

Sub-task 1. Definition of approx. 30 food categories, 20 model migrants, and 3 representative food contact plastics. A selection (including a rationale for this selection) of foods and food groups will be made with the aim to represent all foodstuffs currently on the market, covering their typical solubility and diffusion properties. As model migrants 20 by number will be selected to cover a range of chemical structures, polarities and molecular weights. Then three typical donor plastics will be selected including nonpolar (as for instance polyolefins, PO), medium polar (polyethylene terephthalate, PET) and polar (polyamide, PA) characters.These test systems will be intensively investigated in Task 2 for thermodynamic properties and in Task 3 for logPo/w studies. Selections of substances and plastics will be in consultation with WP4.2.2 where the diffusion properties are studied for the selected model migrants in the selected foods.

Sub-task 2. Extensive experimental studies to determine substance-food-plastic partition coefficients. A standard method will be established, based on the FOODMIGROSURE project, to measure partition coefficients. Food is placed in contact with the plastic at a defined temperature until equilibrium partitioning between the two phases is reached. This process will be monitored over time analytically. With 30 foods/food classes, 20 migrants and 3 temperatures there are 1800 combinations (each in principle being a kinetic curve). Therefore, a reduced set of 350 tests will be designed to achieve the objectives. Analytical methods are available from the FOODMIGROSURE project or will be developed in interaction with WP4.2.2.

Sub-task 3. Experimental confirmation of the available log$P_{O/W}$ values and investigation into the temperature dependency of the log$P_{O/W}$. For the selected model migrants log $P_{O/W}$ values will be sought in the available literature, calculated using freely available software (EPIWIN for instance) and confirmed by experimentation. P10 will study the temperature influence on the log $P_{O/W}$ value to extrapolate the log$P_{O/W}$ / log $K_{P/F}$ relationship to higher temperatures where the food packaging application requires this (e.g. oven use). The expected result is a new "thermodynamic" classification of foods according to their solubility for migrants, which will be established as a (linear?) relationship between polarity of the migrant (log$P_{O/W}$) and its partition coefficient packaging/food, $K_{P/F}$. It is expected that a small number of food categories can represent the thousands of different food items currently on the market and for which food consumption statistics exist.

Sub-Work Package No,	**4.2.2**	**Start date or starting event**		Month 3			
WP Title	Study of effective diffusion properties of foods/food groups concerning as a basis for a 'A_F concept' for foods						
Activity Type	RTD						
Participant Number	3	9	16 (WPL)	21			
Participant Short Name	CSL	FABES	USC	JRC			
Person-months per participant	10	1	31	12			

Overall task of sub-WP. Overall to establish validated diffusion properties of foods as classified in WP4.2.1 in terms of a so-called A_F concept (in analogy to the recognised A_P concept for plastics) by, in particular: by (i) Setting up a sound experimental methodology to get reliable migration data of migrants (model chemicals) in selected food classes; (ii) Elaborating a complete set of experimental data that allows calculating key parameters of diffusion in WP4.2.4.

Description of work

Definitions: Migration modelling is based on estimating the diffusion coefficient of a migrant in the polymer, D_P by using the PIRINGER equation [$D_P = f(A_P, Mw, T)$] A_P is a polymer-specific constant, Mw is the migrant molecular weight and T is temperature. The FOODMIGROSURE project showed that foods behave differently to liquid food simulants with a diffusion-like behaviour of the migrant in the food, expressed as an effective diffusion coefficient in food, D_F. If D_F values could be established through A_F values (characteristic for certain food types by analogy with polymer A_P value concept) then, taken together with the new food classification concept, it would be possible to model migration into foods at a more advanced level. Therefore, diffusion properties of foods will be explored in this WP with the aim to provide comprehensive experimental data sets to allow establishing kinetic key parameters for migration modelling.

Sub-task 1. Establishing analytical methods and the experimental methodology for migration studies. Methods and results from FOODMIGROSURE will be used but as further model migrants and foods will be included, analytical methods need to adapted or developed. (a) review the current analytical methods; (b) propose new analytical methods; (c) trial the proposed methods; (d) demonstrate that the selected analytical methods are fit for the intended purpose.

Sub-task 2. Kinetic migration studies from complex packaging materials into selected foods. Kinetic studies will use multilayer materials doped with model migrants, placed in contact with foods at selected temperatures. For at least six time points the concentration of the migrant in the food will be determined. Studies at 3 temperatures will establish the Arrhenius dependency of D_F and thereby obtain the important "activation energy" necessary to derive A_F.

Sub-task 3. Migrant concentration profile studies. Concentration profiles, i.e. migration concentration in the food as a function of the migration distance into food, will be established. For these studies, a highly doped release matrix (e.g. a wax or polyethylene to mimic the packaging) will be placed in contact with the food. At timed intervals the food will be separated into slices (n= >10) and analyzed. The tests will be run at different temperatures to give the Arrhenius relationship.

Sub-Work Package No.	**4.2.3**	**Start date or starting event**		Month 3			
WP Title	Parameters for multi layer / multi-material migration modelling (reference partition coefficients)						
Activity Type	RTD						
Participant Number	10 (WPL)	9	16	21			
Participant Short Name	Fraunhofer	FABES	USC	JRC			
Person-months per participant	16	2	3	1			

Overall task of sub-WP. To establish a set of reference values for partition coefficients between relevant materials applied for multi-layer / multi-material packaging structures

Description of work
More than 90% of all packaging materials on the market are not homogeneous plastics but rather multi-layer plastics structures or even multi-materials such as paper laminated to plastic. These materials often contain other layers of plastics, aluminium, coatings, adhesives, inks, etc. A chemical from any layer could migrate. Migration modelling cannot currently deal with such multi-layer multimaterials.

Sub-task 1: Measurement of fundamental constants governing the migration process in multi-layer / multi-material structures. Partition coefficients and diffusion constants will be determined experimentally. Relevant multi-layer materials are plastics (PO, PA, PS and PET). Multi-materials will be combinations of paper/board, plastics, coatings, adhesives and printing inks. Model migrants and analytical methods will be taken from WPs 4.2.1 and 4.2.2. Design of Experiment procedures will be used to reduce the number of possible test combinations.

Sub-Work Package No.	**4.2.4**	**Start date or starting event**		Month 6		
WP Title	Migration modelling for multi-layer/multi-material packaging in contact with foods - "$(D/K)_nD_F$" model.					
Activity Type	RTD					
Participant Number	04	09 (WPL)	18	16	21		
Participant Short Name	CEPE	FABES	INCDTIM	USC	JRC		
Person-months per participant	1	6	2	1	1		

Overall task of sub-WP. (a) Development of a migration model for multi-layer / multi-material packaging by using a novel finite difference scheme to solve the system of diffusion equations for a multilayer system in contact with real foodstuffs. (b) Establishment of a comprehensive data set of diffusion and partition constants (D and K) through evaluation of experimental data from WP4.2.1 to WP4.2.3 for reference purposes.

Description of work
Definitions: Migration modelling is now well established for many mono-layer plastics. However, the scientific basis for multi-layer migration modelling is not sufficiently developed. Migration of a chemical from a ML-FCM is controlled by the diffusion within the ML-FCM followed by the transfer into the food, F, and diffusion within this food. A model to describe this should take into account:

- the diffusion coefficients, D_{Pn} , in each layer n of the FCM,
- the partitioning of the substance at the interfaces of the FCM, $K_{Pn-1,Pn}$
- the partitioning of the substance at the FCM-F interface, $K_{Pn,F,}$ and
- the diffusion coefficient, D_F , of the substance in the food

To establish a versatile $(D_{Pn}/K)_n/D_F$ migration model the following tasks will be carried out on the basis of the experimental data provided by and in feed-back interaction with WP4.2-1 to 3:
Sub-task 1. Conceptual setup of the model
Sub-task 2. Mathematical solution of the model
Sub-task 3. Setup of the model for plastic multi-layer materials
Sub-task 4. Implementation of particular layers: paper/board, coatings, adhesives, printing inks.

Sub-task 5. Demonstration of workability of the full migration model
Sub-task 6. Compiling a comprehensive data set of diffusion and partition constants (D and K)

Sub-Work Package No.	**4.2.5**	**Start date or starting event**			Month 9		
WP Title	Probabilistic modelling of concentration of FCM constituents in packed foods & link to exposure modelling in WP8						
Activity Type	RTD						
Participant Number	03	04	9	10	18 (WPL)	21	
Participant Short Name	CSL	CEPE	FABES	Fraunhofer	INCDTIM	JRC	
Person-months per participant	1	1	3.5	1	16	1	

Overall task of sub-WP. (a) To develop a probabilistic migration model able to deliver migrant concentration distributions in foods as a function of the packaging parameter distributions. (b) To establish the appropriate link to the exposure model developed in WP8, such as to allow integration of the probabilistic migration model into the exposure model.

Description of work
Sub-task 1. Conceive and design of the probabilistic model. The deterministic migration modelling described in WP4.2.3 is intended to be conservative. In practice, there will always be a variation of the parameters influencing migration. So migration levels in foods are not fixed (upper bound points) but rather are distributions. Stochastic models, also called probabilistic models, will be invoked to take account of this by predicting the most probable outcome based on data from earlier experiments.
Sub-task 2. Integrate the deterministic migration model developed in WP4.2.4 into the probabilistic migration model. We will use probability distributions that show which migration values are the most likely to occur in a given food/packaging combination. The stochastic models will take into account the inherent input variability regarding packaging thickness, area to volume ratio, diffusion properties, partitioning into food, storage time and temperature between packaging the food and unwrapping it to eat, etc. This information will come from WP4.1.
Sub-task 3. Establish the method of data communication between the probabilistic migration model and the exposure model developed in WP8.

Work Package Number	**4.3**	**Start date or starting event**					Month 1
WP Title	Use of QSAR modelling for the migrants from food packaging						
Activity Type	RTD						
Participant Number	03 (WPL)	04	21				
Participant Short Name	CSL	CEPE	JRC				
Person-months per participant	14	6	1				

Objective
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.

Description of work
CSL, the JRC and the industrial participants of CEPE, have extensive background knowledge and expertise in the use of QSAR in various fields. They will use their world-wide networks to help ensure that the QSAR approaches adopted will gain general acceptance by risk assessment and regulatory authorities such as the EFSA and the Commission.

One or more of the commercial QSAR programmes (e.g. TOPKAT, Derek-4W, MultiCASE, MC4PC, MDL, etc) will be used for the prediction of toxicity. The choice will be informed by the ongoing discussions on guidelines for QSAR being developed within OECD. These programmes use a range of quantitative structure-toxicity relationship models for assessing specific toxicological endpoints – including carcinogenicity, mutagenicity, maximum tolerated dose, LD_{50}, and LOAEL (lowest observable adverse effect level). As a measure for general toxicity a LOAEL module will be used.

Task 1. First, the model(s) will be validated with Food Contact Substances (additives, monomers, oligomers) of known toxicity. The packaging - specific learning set will comprise a target of n=200 substances. The LOAEL for each substance will be estimated and the results compared with published, long term toxicity data. The accuracy of the predictions will be calculated. An accuracy of 80-90% will be the target. This may depend on the chemical class of compounds. The reliability criteria of the modelling decisions will be decided in consultation with the Project Stakeholders.

Task 2. The research will be extended to other endpoints of toxicity - most crucially mutagenicity. Assessment for genotoxicity potential is the critical decision in the assessment of NIAS (not intentionally added substances) in food packaging materials. The predictive capabilities of the model(s) will be tested against published experimental data on mutagenicity (target n=200 substances) and also compared with decisions made by other expert systems. Accuracy criteria of the modelling decisions will be decided in consultation with the Project Stakeholders. It is proposed that the target be, that no more than 10% of negative (not-toxic) predictions are false negatives for mutagenicity and no more than 50% of positive (toxic) predictions are false positives. This balance is precautionary and favours consumer protection.

Task 3. By means of a small subcontract, the QSAR equations will be recalculated / recalibrated to improve if necessary the predictive capabilities. The recalculated QSAR equations will be revalidatied for both NOAEL and mutagenicity using a second-set of target n=100 packaging substances.

No.	Deliverables	Month
4.3	Report on verification of QSAR approach for migrants from food packaging materials.	32

Work Package Number	**5**	**Start date or starting event**			Month 6	
WP Title	Food intake database collation and targeted food frequency studies					
Activity Type	RTD					
Participant Number	2	1	6	7	11	22	17
Participant Short Name	UU	UCD	AFSSA	INRAN	KTL	FCNAUP	IZZ
Person-months per participant	23	3	6	12	8.6	7	6
Participant Number	13	4					
Participant Short Name	CFRI	CEPE					
Person-months per participant	6	1					

Objectives

1. To compile a database on food intake across geographically representative regions of the EU based on existing databases
2. Newly created targeted food frequency questionnaire studies

Description of work

Task 1. Information on food consumption databases from the 8 identified geographical regions of the EU collated.

Task 2. Analysis of methods of data collection, food grouping systems, linguistic definitions of food groups across EU databases. Following the identification of the target food chemicals by the "Food chemicals" group, discussions will begin on how existing databases can be adopted to a tiered collated EU food intake database which takes account of the variability in the level of detail with which food intake is recorded in different countries. Care will be taken with linguistic variability in definitions of foods and food categories (Partners 1, 2, 6, and 7). The development of guidelines for the use of the new food intake database including such issues as the appropriate use of total population data and consumers only data, the use of broad and narrow definitions of food categories, the extrapolation to higher percentiles of intake and a range of other issues which will ensure that that the subsequent use of the database is fully informed of the limitations and capabilities of the database (Partners 1,2,6,7 and 11).

Task 3. Identify EU countries from the 8 representative regions which have limited food consumption data

Task 4. Create targeted FFQ's for specific EU countries where food consumption data limited. Liaise with WP 2, 3, 4, 6 & 7 to create FFQ's.

Task 5. Administer targeted FFQ's in specific countries to specified number of people. Compilation of results. Partners from EU countries, where food intake data is somewhat limited will in this task carry out limited and targeted food frequency questionnaires which will help yield a more substantial database on food intake. This will also feed into Workpackage 7 (Partners 11, 13, 17 and 22).

No.	**Deliverable**	**Month**
5.1	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.	36
5.2	Guidelines for the appropriate use of the harmonized database	36
5.3	A report on the value of targeted ancillary food frequency questionnaires for the estimation of food chemical intake	42

Work Package Number	**6**	**Start date or starting event**				Month 13
WP Title	Food Chemical Occurrence Database					
Activity Type	RTD					
Participant Number	1	2	6	7	11	22	17
Participant Short Name	UCD	UU	AFSSA	INRAN	KTL	FCNAUP	IZZ
Person-months per participant	28	10	8	12	14.6	13	12
Participant Number	13	4					
Participant Short Name	CFRI	CEPE					
Person-months per participant	12	3					

Objectives

1. To construct a database on the occurrence of selected food additives, food flavouring substances and food contact materials in representative regions of the EU

Description of work

Partner 1 will lead these tasks, with data collection also from Partners 2, 6, 7, 11, 13, 17 and 22).

Task 1: Based on the input of the three "food chemical" groups, a list of target food categories will be drawn up for which chemical occurrence data will be sought. Each partner will purchase a significant percentage of the main brands in each food category and will draw on local advice as to the brands with the largest market share. The packaging will be photographed using a digital camera creating a reference library of such and the ingredients listed on the package will be entered into a food ingredient database. Where nutritional information is available, that will be recorded. The food ingredient database will be built on the experience of the coordinator who uses an Access database structure. The packaging will be isolated and described initially in terms of food contact material as glass, paper, metal and plastic.

Task 2: The packaging experts (CEPE) will be asked to assist in training the researchers to recognise particular type of contact material such as plastic lining of a metal can. A sample of the packaging will be taken and stored for future reference and where needs verification. Any data on the package relating to flavouring will be recorded in addition to whatever is contained within the ingredient box.

No.	**Deliverable**	**Month**
6.1	A harmonised database on targeted food chemical occurrence in 8 member states	36

Work Package Number	**7.1**	**Start date or starting event:**	Month 1
WP Title	Development and Validation of Regional Food Consumption Models; Food Grouping systems. Model design and testing		
Activity Type	RTD		

Participant Number	5	15	3	22	17	13	11
Participant Short Name	FCRA	CREMe	CSL	FCNAUP	IZZ	CFRI	KTL
Person-months per participant	6.5	32	23	8	6	6	8.1
Participant Number	1	4	1				
Participant Short Name	UU	CEPE	UCD				
Person-months per participant	4	3	2				

Objective: Collaborate with other WPs to develop suitable food grouping systems and a modeling framework for estimating consumption for the defined food groupings for all EU member states, and test the method with known data sets.

Description of work

Task 7.1.1 – Development of food grouping systems

1. WPs 2,3 and 4 will be collaborating with WPs 5 and 6 to develop food grouping systems for the classification of foodstuffs in which additives or flavourings are used and different types of food packaging applications. The food grouping systems will be used to collate infomation about food consumption and the occurrence of additives, flavours or food contact material migrants. Because different food consumption surveys contain different levels of detail it will be necessary to develop a hierarchical approach. For WP7 it will be 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 should allow for a sufficiently detailed approach whilst bearing in mind the practical limitations of including large numbers of highly specified foods. It may be necessary to limit the model to certain critical foods, as identified by WPs 2, 3 and 4 (FCRA, CREMe, CSL, CEPE, FCNAUP, KTL, IZZ & CFRI).
2. WP5 will be gathering available European food consumption data. It will be necessary to liaise with this WP to identify compatible age-banding for food consumption modelling (FCRA & UU).

Task 7.1.2 – Model development

1. Identify country and food groupings for which consumption estimates are not presently available. For example, several European countries have information about average consumption of certain foods derived from household expenditure surveys. However, these data are not readily converted to estimates of the amounts individuals of different ages consume (FCRA).
2. Identify other countries in same EU region that have detailed individual food consumption surveys: these will be used as a starting point for extrapolation to the country of interest. Obtain relevant survey data from WP5 (FCRA).
3. Use the detailed surveys to provide prior estimates for consumption of the food groupings of interest (FCRA).
4. Identify available quantitative information (e.g. food frequency questionnaires, household basket surveys, marketing data) for the country of interest obtained by WP7.1.1. Combine these data with the prior estimates using appropriate methods (e.g. Bayesian updating) and provide improved estimates population groups within the country of interest (CSL, CEPE & CREMe).
5. Liaise with WP5 to identify national experts in the country of interest with special knowledge of consumption patterns for the food groupings of interest. Present them with the estimates from step (4) and targeted questions to elicit additional information from the expert,

using formal expert elicitation techniques. Use the results of this to further update and improve the consumption estimates for the country of interest (CSL, crème, FCRA, CEPE, KTL, IZZ & CFRI).
Task 7.1.3 – Method testing
Test and validate the approach developed in WP7.1.2 by using it to estimate consumption in two example countries in different regions of the EU. The countries selected for this task will all have detailed consumption surveys, so that predictions can be validated by comparison with actual data. So, for example, Irish National food consumption data would be used as the basis for extrapolation to the UK using UK HBS and other data. The results would be compared with the 'true' results derived from UK individual food consumption survey data. After each test the database and extrapolation model would be revised to improve the approach as necessary (FCRA, CSL, CEPE & CREMe).

No.	Deliverable	Month
7.1	European model for extrapolation of national food consumption patterns	30

Work Package Number	**7.2**	**Start date or starting event:**			Month 30
WP Title	Development and Validation of Regional Food Consumption Models; Food Frequency Questionnaire and Model Validation				
Activity Type	RTD				
Participant Number	5	15	3	4	
Participant Short Name	FCRA	CREMe	CSL	CEPE	
Person-months per participant	5	4	7	1	

Objectives: 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 modeling.

Description of work
Task 7.2.1 – Validation
1. The approach developed in WP7.1 will be applied to representative countries in each EU region. For each country, estimates for food groupings identified in WP7.1, sub-divided by appropriate age bands will be produced. Specific foods will be selected from the food groups that are marketed in uniform product sizes (e.g. certain soft drinks), so that food frequency data can provide a reasonable estimate of consumption (CREMe & CSL).
2. Liaise with national experts in WP5 to obtain new food frequency data for the selected groupings and sub-populations, and use this to verify the model outputs (FCRA).
Task 7.2.2 – Database development
1. Organise the results in a refined food consumption database, to be linked in to the database and models in WP8, used in case studies in the project, and made available to end-users. The content and format of the database will be designed to complement and extend the basic consumption data format provided by the EFSA concise database, so as to facilitate their use within risk assessment procedures. Data will be presented as point estimates (mean, percentiles) for each food category and age-group as in the EFSA concise food database model. Data will also be presented in a distributional format that can be applied in probabilistic models (FCRA, CSL, CEPE & CREMe).
2. The validity of combining high percentile intakes from one or two foods with the average from the rest of the diet, to estimate total high level consumption, will be investigated (FCRA, CSL & CREMe).

No.	Deliverable	Month
7.2.1	Database of national food consumption	42
7.2.2	WP7 Validation report on the database of national food consumption	48

Work Package Number	**8**		**Start date or starting event**			Month 1		
WP Title	Development and Validation of Dietary Intake Models, Databases and Interface for End-Users							
Activity Type	RTD							
Participant Number	15	3	4	9	21	11	7	6	1
Participant Short Name	CREMe	CSL	CEPE	FABES	JRC	KTL	INRAN	AFSSA	UCD
Person-months per participant	80	21	6	2	7	3.6	3	3	1

Objectives

1. To develop practical yet innovative alternatives to the current simplistic and criticised first-tier exposure models in each area: flavourings (WP 2), additives (WP3), and packaging (WP 4)
2. 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.

This WP is divided into sub workpackages 8.1 and 8.2

Work Package Number	8.1		Start date or starting event:			Month 1		
WP Title	Model design and Validation, algorithm development, uncertainty analysis and software integration							
Activity Type	RTD							
Participant Number	15	3	4	9	21	11	7	6	1
Participant Short Name	CREMe	CSL	CEPE	FABES	JRC	KTL	INRAN	AFSSA	UCD
Person-months per participant	62	18	5	2	7	3.6	3	3	1

Objectives

1. Develop models, algorithms and integrate the exposure assessment tool to handle the available data and uncertainty and for Partner 15 to provide an online system for data collection and collaboration.
2. To work with food experts in WP 2, 3, 4 and the data generated in the project to validate the models developed.

Description of work

Task 1: CREMe and CSL will consult with expert groups in each area (WP2, 3, 4) (CREMe, CSL, FABES, CEPE, UCD, INRAN, AFSSA, KTL) to understand the data limitations and uncertainty to start the development of models to handle exposure assessments across Europe.
Task 2: CSL and CREMe will develop algorithms and tools for dealing with uncertainty and expert elicitation,
Task 3: FABES will focus on development of packaging migration models including uncertainty in the models. CREMe will commence development of central PC based modelling software.

Task 4: Model development and will continue throughout the project as feedback becomes available and refinements are required. CREMe will integrate the modules from CSL and FABES into the central model (CREMe, CSL, FABES). The modelling team will together develop and apply algorithms to model the exposure in the three key areas packaging/flavour/additive. This work will be done in close collaboration with the experts in these disciplines in work packages 2, 3 and 4 using a combination of formal expert elicitation and Bayesian analysis refinement of the models and treatment of uncertainty will continue throughout the project as more data becomes available.
Task 5: CREMe and CSL will work with experts from the 3 key areas and pan European modelling group to validate the models (CREMe, CSL, FABES, CEPE, FCRA, UCD, INRAN, AFSSA, KTL). In order to validate the models, the group will compare the predictions of the models to real values which are generated from detailed data where available. Where no "real values" are available, the models will be evaluated by expert peer review.
Task 6: JRC will work with the modelling groups (CREMe, CSL, FCRA and FABES) throughout the project to discuss information on the state of the art of other on-going projects in the area of exposure to chemicals with a view to future sustainability of the modelling tool. . Examples will include HEIMTSA (Health and environment integrated methodology and toolbox for scenario assessment) and EIS-Chemrisks for examples as both are toolboxes. Although current deterministic methods are thought to be conservative – or perhaps over-conservative – their true relation to actual intakes has not been established. The probabilistic models and data developed in this project will be used to calibrating existing deterministic methods to establish the level of protection of these tools.
Task 7: CREMe, CSL, CEPE and FABES will work together to refine and improve the models based on end user feedback and the validation studies. A model validation report will be generated by the group.

No.	**Deliverable**	**Month**
8.1.1	Draft exposure assessment software tool for external evaluation	32
8.1.2	Final exposure assessment software tool, PC based and publicly available	42
8.1.3	Model Validation Report	48

Work Package Number	**8.2**	Start date or starting event:				Month 6	
WP Title	Online Database Manager						
Activity Type	RTD						
Participant Number	15	3	4				
Participant Short Name	CREMe	CSL	CEPE				
Person-months per participant	18	3	1				

Objectives
1. To provide an online system for data collection and collaboration for the project.
2. To work with food experts in WP 2, 3, 4 and the data generated in the project. To validate and refine the models developed

Description of work
Task 1: The modelling groups (CREMe, CSL, FCRA and FABES) with CEPE will initiate a discussion at the start of the project to understand what is required from the three expert groups (additives, flavourings and packaging materials), this discussion will be ongoing throughout the project to obtain feedback on the development.

Task 2: Further end user interaction will be incorporated via communication with the plenary committee of member states. Questionnaires will be sent to each group requesting requirements and feedback at an early stage of model development.
Task 3: CREMe will use its pre-existing IP to provide a central web based data management system for data collection and online collaboration.
Task 4: The modelling team will deliver PC-based software and will work with each of the three expert groups to perform data analysis and exposure assessments, results will be reported, methodology and manuals developed, and handover of tool to end users will be facilitated. (CREMe, CSL, UCD, INRAN, AFSSA, CEPE).

No.	Deliverable	Month
8.2.1	Exposure analysis report	48

Work Package Number	**9**	**Start date or starting event**					Month 6
WP Title	Concentration data						
Activity Type	RTD						
Participant Number	19						
Participant Short Name	CIAA						
Person-months per participant	18						

Objectives
1. To provide a database on the likely technological use of selected food additives in targeted foods
2. To populate database with additive concentration ranges

Description of work
Task 1: Partner 19 will work with WP 3 in concluding a list of target additives and defining the relevant food categories for these additives for which probabilistic exposure assessment will be made. Once the list of targeted additives and food categories are available, Partner 19 will through its extensive committee structure and its many specialised food trade associations to identify experts in the technology of particular foods who can advise on typical technological use of the targeted food additives in each targeted food group.
Task 2: For each additive, a brief one to two page dossier will be prepared which will outline the likely range of concentration of each additive and will list reasons related to typical composition of the target food which would see the upper, middle or lower end of technological use be preferred.
Task 3: Partner 19 will then work with WP 3 (Additives), WP 6 (Chemical occurrence) and WP 8 (Databases & Modelling) to develop appropriate algorithms for deterministic and probabilistic exposure modelling.

No.	**Deliverable**	**Month**
9.1	Database on the technological use and ranges of food additives selected for study within the FACET project	36

Work Package Number	**10**	**Start date or starting event**				Month 1	
WP Title	Dissemination						
Activity Type	OTHER						
Participant Number	1	15	21	4			
Participant Short Name	UCD	CREMe	JRC	CEPE			
Person-months per participant	10	2	7	3			

Objectives

1. 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
2. To disseminate the development results from the software models developed in WP8.

Description of work

The dissemination workpackage will entail the establishment of an effective communication process to end users. The main areas of activity will be:

Task 1. To establish and maintain a communications programme. This will include the development of an effective logo and a website for the project, and management of an annual project dissemination programme. WP leaders will submit results, data and information to fulfil dissemination schema.

Task 2. Dissemination of develoment results from the project. CREMe will provide training for the end project users involved in data collection and support and maintenance of the online tool. Dissemination materials will be developed and training in the use of the models and software tools will be given to end users from the member states. JRC as part of Commission will contribute to the dissemination of results of the project in the field of food safety; specifically, via the Network of CRLs-food safety under Regulation 882/2004 on Official Feed and Food Controls and through the final Conference organisation. In addition, the dissemination materials will be disseminated via all JRC Networks dealing with food, as well as via specialised press. JRC will organise the final Symposium. CEPE in cooperation with other WP10 partners, will disseminate information etc to industry and others through the industrial partner's network in order to maximise the dissemination.

No.	**Deliverable**	**Month**
10.1	Establishment of the project website	5
10.2	Produce a logo for the project and flyers to communicate information about the project	9
10.3	Training manual for software	42
10.4	Final plan for dissemination	48

B.1.3.6 Efforts for the full duration of the project

Project Effort Form 1 - Indicative efforts per beneficiary per WP

Workpackage	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	TOTAL per Beneficiary
UCD	40	1	3		3	28	2	1		10	88
UU		1	1		23	10	4				39
CSL				48			30	21			99
CEPE				53	1	3	4	6		3	70 *
FCRA			6				11.5				17.5
AFFSA			48		6	8		3			65
INRAN		65			12	12		3			92
TUM		28									28
FABES				13				2			15
Fraunhofer				50							50
KTL					8.6	14.6	8.1	3.6			34.9
STFI.PF				31							31
CFRI					6	12	6				24
FCNAUP					7	13	8				28
CREMe			2				36	80		2	120
USC				40							40
IZZ					6	12	6				24
INCDTIM				18							18
CIAA			16						18		34
JRC				30				7		7	44
TOTAL	40	95	76	283	72.6	112.6	115.6	126.6	18	21	961.4

* CEPE are not a beneficiary of any direct EU funding. This will be in kind time contribution.

Project Effort Form 2 - indicative efforts per activity type per beneficiary[6]

Activity Type	UCD	UU	CSL	CEPE*	FCRA	AFSSA	INRAN	TUM	FABES	Fraunhofer	KTL
RTD/Innovation activities											
Flavourings	1	1	0	0	0	0	65	28	0	0	0
Additives	3	1	0	0	6	48	0	0	0	0	0
Packaging	0	0	48	53	0	0	0	0	13	50	0
Food intake	3	23	0	1	0	6	12	0	0	0	8.6
Chemical occurrence	28	10	0	3	0	8	12	0	0	0	14.6
Regional modelling	2	4	30	4	11.5	0	0	0	0	0	8.1
Databases and modelling	1	0	21	6	0	3	3	0	2	0	3.6
Concentration data	0	0	0	0	0	0	0	0	0	0	0
Total 'research'	38	39	99	67	17.5	65	92	28	15	50	34.9
Demonstration activities											
Total 'demonstration'	0	0	0	0	0	0	0	0	0	0	0
Consortium management activities											
Project management	40	0	0	0	0	0	0	0	0	0	0
Total ' management'	40	0	0	0	0	0	0	0	0	0	0
Other activities											
Dissemination	10	0	0	3	0	0	0	0	0	0	0
Total 'other'	10	0	0	3	0	0	0	0	0	0	0
TOTAL BENEFICIARIES	88	39	99	70	17.5	65	92	28	15	50	34.9

* CEPE are not a beneficiary of any direct EU funding. This will be in kind time contribution.

[6] Please indicate in the table the number of person months over the whole duration for the planned work , for each work package, for each activity type by each beneficiary

Activity Type	STFI	CFRI	FCNAUP	Creme	USC	IZZ	INCDTIM	CIAA	JRC	TOTAL ACTIVITIES
RTD/Innovation activities										
Flavourings	0	0	0	0	0	0	0	0	0	95
Additives	0	0	0	2	0	0	0	22	0	82
Packaging	31	0	0	0	40	0	18	0	30	283
Food intake	0	6	7	0	0	6	0	0	0	72.6
Chemical occurrence	0	12	13	0	0	12	0	0	0	112.6
Regional modelling	0	6	8	36	0	6	0	0	0	115.6
Databases and modelling	0	0	0	80	0	0	0	0	7	126.6
Concentration data	0	0	0	0	0	0	0	12	0	12
Total 'research'	31	24	28	120	40	24	18	34	44	899.4
Demonstration activities										
Total 'demonstration'	0	0	0	0	0	0	0	0	0	0
Consortium management activities										
Project management	0	0	0	0	0	0	0	0	0	40
Total ' management'	0	0	0	0	0	0	0	0	0	40
Other activities										
Dissemination	0	0	0	2	0	0	0	0	7	21
Total 'other'	0	0	0	2	0	0	0	0	7	21
TOTAL BENEFICIARIES	31	24	28	120	40	24	18	34	44	961.4

B.1.3.7 List of milestones and planning of reviews

List and schedule of milestones

Milestone no.	Milestone name	WPs no's.	Lead beneficiary	Delivery date from Annex I	*Comments: Internal sources of verification*
1	A sampling and analysis plan to verify output of WP 4.1.1	4.1	3	6	Publicly visible
2	Convening an expert group on additive concentration	3 & 9	6	6	Minutes of meeting
3	Secure Central Data Management System Customised and Online	8.2	15	9	Online tool will be verified by date input groups
4	Agreement on target food categories	2,3,4,5,6	2	12	Final list of target food categories
5	List of target flavouring substances available	2.1	7	12	Final list of target flavouring substances
6	List of additives for concentration data.	3 & 9	6	12	Final list of target additives
7	Agree categories of foods at different tiers of precision.	5 & 7	2	12	Agreed tiered list of food categories
8	Commence additive data collection.	9	19	12	List of target additives in target food categories to be collected
9	Agree software structure and training of staff for occurrence data	2,3,4,5,6	1	15	Project notification
10	Purchase of foods for occurrence data	6	1	15	Food Ingredient Database
11	Feedback on suitability of existing QSAR software for packaging substances along with plan for improvement	4.3	20	15	Feedback report
12	Database of reported concentration level of target flavouring substances in food populated	2.3	7	18	Project notification
13	Working list of substances in packaging materials.	4.1	3	18	Publicly available
14	Creation of a tiered food intake database.	5	2	18	Report on tiered food intake
15	Agreement on questionnaires on food additive levels.	3 & 9	6	24	Minutes
16	Initial feedback on variation in packaging over time for a given country and variation between countries	4.1	3	24	Feedback documented
17	Agree targeted foods for targeted Food Frequency Questionnaires.	2,3,4,5	2	24	Finalised FFQs
18	Completion of food grouping system and basic food consumption database	7.1	2	24	Publicly visible
19	Expansion of the deterministic migration model into a probabilistic model	4.2	10	28	Testing & validation of the application software
20	Completion of model testing	7.1	5	30	Report on model

21	Incorporating the probabilistic migration model data into the exposure model	4.2	10	32	Successful data communication to the exposure model
22	Complete targeted Food Frequency Questionnaires.	5	2	36	FFQ database
23	Completion of food chemical occurrence database	2,3,4,6	1	36	Website
24	Populate database with additive concentration data.	9	19	36	Concentration database complete
25	Completion of FFQ model validation	7.2	5	40	Report of model validation
26	Completion of European food consumption model and database	7.2	5	42	Website
27	Packaging materials and substances linked with different foodstuffs and concentration data	8	15	48	List of links between packaging materials, foods & concentration data
28	Organisation of the final conference.	10	8	48	Minutes of final conference

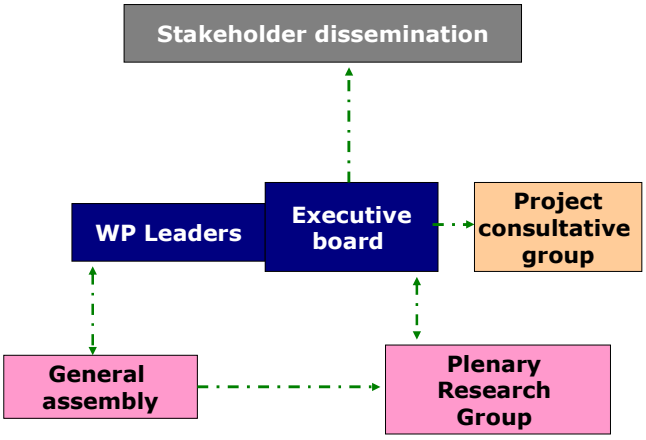
Tentative schedule of project reviews

Review no.	**Tentative timing, i.e. after month X = end of a reporting period**	***planned venue of review***	***Comments , if any***
1	After project month: 24	Brussels	
2	After project month: 48	Brussels	

B2. Implementation

B.2.1 Management structure and procedures

The overall organisation of the management structure is given below.



- The **partners** are organized into the General Assembly which will meet during the Plenary Research Group meeting. This is the only forum where all partners meet to discuss the project and to reach decisions according to the rules of the Consortium Agreement. The meetings of the General Assembly will always be held at that period of the year when work is about to commence on the preparation of the 18 month activity and administrative reports to the Commission.
- The **Plenary Research Group** comprises all the partners and all of the contract research staff employed directly or indirectly in the project. During the meetings of the Plenary research Group which will generally last 2 days, all work package leaders will make presentations of the work in progress, will identify any risks to the project and will give an overview of research output. During such meetings, training sessions will be held where required.
- The **Executive Board** is made up of the various work package leaders. This is the key group who will manage the project chaired by the coordinator. It will meet as often as the management require, generally 2-3 times annually usually for 1 day whether in situ or via teleconference. The project management group will second a representative of the consortium of companies who are co-investing in FACET (see section 2.3). The duties of the Executive Board will be laid down in the Consortium Agreement but its main area of activity is the coordination of the project in between the General Assembly meetings.
- A **Project Consultative Committee** will be established by the Executive Board and efforts will be made to meet some or all of the Consultative Committee once a year, preferably back to back with a meeting of the Executive Board. Among the groups who will be asked to nominate a member are: EFSA, DG SANCO, WHO/FAO/JECFA, industry, consumers and some specialist experts as needed. The Consortium Agreement will make it clear that the Project Consultative Committee will serve to assist the Executive Board in making contacts with

experts, in gaining access to draft documents that are relevant to the project and in other ways as they arise. The project consultative committee is not a project review committee nor a committee that will maek decisions or the project, although the Executive will always be willing to listen to critical advice which will help improve the overall success of the project.

- **Timing of proposed meetings within the project:** All partners will attend a plenary meeting. These will be held at month 0-3 ('kick-off meeting'), month 18, month 36 (plan for dissemination) and at month 48 (dissemination meeting). Members of the Executive board will also be expected to attend an additional 4 meetings at month 6, month 12, month 24 and month 42 (some of these meetings will be teleconferences).

B.2.2 Beneficiaries

Partner 1. University College Dublin IRL (UCD)

Organisation/Laboratory:

UCD is the largest university in Ireland and is in the process of uniting all its food- related activities into a new UCD Institute of Food and Health of which Professor Mike Gibney will be the coordinator. This Institute comprises activities in food science, nutrition, food safety, food engineering, food law and consumer science in relation to food and health. Some 25 full time academics and 150 researchers will make up the Institute. UCD is the highest earner of national and EU funds in food-related research in Ireland. Probabilistic modeling of food borne risks is an integral part of several areas of the Institute.

Role in the project

UCD will be the overall project coordinator and will be responsibility for coordinating WP on "chemical occurrence"

Scientific and technical team and its experience in relation to the project

Professor Mike Gibney is the lead scientist in the area of estimating consumer exposure to food borne chemicals. He was coordinator of two consultative reports on food additive intake assessment in the early 1990s and coordinated the Scientific Cooperation (SCOOP) Task 4.2 and participated in SCOOP task 4.1. He has published on exposure assessment for all of the three categories of chemicals named in the call. He coordinated the FP5 MonteCarlo project (http://montecarlo.tchpc.tcd.ie/) which developed validated probabilistic models and validated software for the exposure assessment of food additives, pesticides and nutrients. In FP6 he coordinated a workpackage on exposure assessment to novel foods in the Noforisk project (www.noforisk.org). In terms of experience of leading large projects, he is coordinator of the FP6 IP Lipgene project (www.lipgene.tcd.ie) with 24 partners and budget of €12.5m. This project is now entering year 4 and will be now winding down. From national research budgets, Professor Gibney has significant funding for pesticide exposure assessment, for a national food ingredient database, for a national database on packaging use and for additive and packaging material exposure assessment. He has published papers on probabilistic modeling to all three of the target chemicals in the call. For this project he will be joined by Áine Hearty who has worked on exposure assessment to novel and Gm foods in the Noforisk project and by Aileen Connolly who is working on the national food ingredient database, the national packaging database and with Áine Hearty on pesticide and additive exposure assessment.

Partner 2. University of Ulster, UK (UU)

Organisation/laboratory

The Northern Ireland Centre for Food and Health (NICHE) has achieved 5* ratings for research in the (1998 & 2001) UK-wide University Research Assessment Exercises. NICHE has 50 staff working on nutrition research and has a significant number of formal collaborations with research institutes and universities throughout the world. In the EU we have formal links with Finland, the Netherlands,

Denmark, Belgium, Sweden, Italy, France, Germany, Spain, Greece, the Rep. of Ireland, and throughout the UK. Currently, recipient of EC grants for Framework 5 and 6.Partner in IUNA Irish Universities Nutrition Alliance North/South Ireland Adult Food Consumption Survey (NSIFCS). The survey investigated habitual food and beverage consumption, in a representative sample (n=1379) of the adult population in the Republic of Ireland and Northern Ireland. A food consumption database was constructed which allowed further research on food intake and exposure assessment to be conducted.

Role in the project: Coordinate WP5. To compile a database on food intake across geographically representative regions of the EU based on existing databases and newly created targeted food frequency questionnaire studies.

Scientific/technical team and its experience in relation to the project:

Professor Sean Strain: Co-Director of the Centre for Molecular Biosciences at the University of Ulster, Author of 175 peer-reviewed research publications mainly in the areas of trace element nutrition and in B vitamin and homocysteine metabolism. Member of the Royal Irish Academy. Member of the EFSA Panel on dietetic products, nutrition and allergies [NDA] Co-ordinator of EU funded project, FOODCUE, currently partner on EU funded projects Zenith and FEMMES –specialising in trace element research.
Professor Barbara Livingstone: DPhil Human Nutrition, Professor of Nutrition at the Northern Ireland Centre for Food and Health. Research in the area of dietary assessments of free-living populations, appetite regulation and dietary and lifestyle risk factors for childhood obesity. She has published 74 original peer-reviewed publications.
Dr. Aideen Mc Kevitt: Industrial Microbiology, Food Microbiology, Education, Medical Science (Ph.D). Course Director M.Sc Food Regulatory Affairs developed by Irish Universities Nutrition Alliance. Research in Food Regulatory Affairs. Experience in managing EU Projects: Irish Lead Laboratory and Project manager EQUASE Extend Quality Assurance in water microbiology to cohesion countries. Project manager: EU Commission funded Leonardo da Vinci project- Curriculum development in Regulatory Affairs.

Partner 03. Central Science Laboratory, York, UK (CSL)

The organisation/laboratory: CSL is an executive agency of the UK Department for Environment Food and Rural Affairs (Defra). CSL is a world-class facility with a science staff of about 450. CSL has certification for compliance to ISO 9001: 2000. The scope of activities covered by the certification includes the provision of scientific services in the areas of agriculture, food and the environment to government and non-government customers worldwide.

Role in the project:
Overall coordinator of WP4, dealing with all aspects of work concerning food packaging materials.

Scientific/technical team and its experience in relation to the project:
CSL has an unrivalled record of research, method development and analysis of packaging materials and foods, extending back over 25 years. Its scientists are active members of various EFSA, EU, FSA (UK) and CEN committees. This understanding of EU regulations and risk assessment makes CSL unique in this field.
Laurence Castle. A chemist by training. Member since inception in 2003 of the EFSA AFC panel on food Additives, Flavourings and Food Contact Materials. Convenor of CEN TC194-SC1 and its 5 working groups dealing with testing for migration from plastics. Member of the DG-SANCO Expert

Group on food contact materials. Broad food safety experience and has published more than 150 journal papers on packaging migration, food additives, processing contaminants etc.

Andy Hart. An environmental biologist by training. Member since inception in 2003 of the EFSA PPR panel on Plant Protection Products and their residues.. Leading contributor to the EFSA *Guidance on Uncertainty in Dietary Exposure Assessment* (2006). Heads the CSL Risk Analysis Team which specialises in development and application of quantitative methods for analysing risk and uncertainty, including Monte Carlo and Bayesian approaches. Has successfully applied these methods in a range of areas including environmental risks of pesticides (FP5 project EUFRAM, www.eufram.com, www.webfram.com), risk benefit analysis (FP6 project QALIBRA, www.qalibra.eu) and packaging migration.

Emma Bradley. A chemist by training. Heads the packaging migration team at CSL which is the UK NRL. Member of the CRL-NRL network on Food Contact Materials (Community- and National-Reference Labs).

Other staff members drawn from their respective teams.

Partner 04. FACET Packaging Industry Group, BE (CEPE))

Organisations:

Industry formed a Vision Exposure Group some years ago to address consumer exposure to migrants from food contact materials. This group has been pro-active in initiating exposure modelling work and the collection of food packaging usage data for some European countries. The Vision exposure group has decided to fully support FACET by the provision of funding and expertise. To do this it has formed the FACET Industry Group (FIG) with offices located at CEPE in Brussels (BE). FIG consists of industry sectors covering plastics, metal and paper/board packaging with other packaging materials expressing an interest to participate. Thus the actual list is most likely larger than that given here.. . Being represented at the trade association level allows the interests of SMEs to be fully protected. For example, one of the partner trade associations (EUPC) represents the interests of 37,000 packaging SMEs. FIG has been structured to utilise the expertise of its various members. There is an overall chair (Peter Oldring) and three sectors, namely plastics, metal and paper/board, are each represented by a deputy chair. The three sectors are further subdivided into flexible and rigid plastics, coated and uncoated metal, paper/board and laminated paper/board. These technical experts form part of an industry steering group.

Role in the project:

WP4. Expertise on packaging materials and their use and composition rests largely with industry. The industry participants will guide the project at all stages, they will input the information and findings of their on-going 3 exposure-related projects, they will provide information on packaging composition and usage gathered from their own members, and they will advise on how best to obtain and interpret data for 27 member states including extrapolation to fill data gaps.

Scientific/technical team and its experience in relation to the project:

Dr. Peter Oldring, Director Regulatory affairs – Europe (Valspar - a major can coating company) has a BA in Chemistry and a PhD in polymer chemistry and has co-authored/edited 18 text books on resins and surface coatings and numerous articles/papers. He is actively involved in regulatory issues surrounding food packaging. He was a founder member of the JIG (Light metal packaging Joint Industry Group) and chaired the group who wrote the Coatings Code of Practice. He chaired the Vision exposure project. He is a member of the ILSI expert group who are preparing a monograph on exposure from FCMs.

Three deputy chairs. Six packaging sector representatives. Twelve Trade Associations. The industry participants are all experts in their particular fields of packaging. This list is expected to increase as other packagiung sectors become involved. This is all to the benefit of of all involved in the project. Details of the membership and constitution of FIG are as follows:

- APEAL (Association of European Producers of Steel for Packaging), having its registered office at Av Louis 89, 1050 Brussels (Belgium) – represented by Jean-Pierre Taverne
- CEPE (Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art), having its registered office at Av van Nieuwenhuyse 6, 1160 Brussels (Belgium) – represented by Jacques Warnon
- CEPI (Confederation of European Paper Industries), having its registered office at Av Louise 250, 1050 Brussels (Belgium) – represented by Nigel Barnwell
- CiAA (Confederation of the Food and Drink Industries in the EU), having its registered office at Avenue des Arts, 43, 1040 Brussels (Belgium) – represented by Beate Kettlitz
- EAA (European Aluminium Association), having its registered office at Av de Broqueville 12, 1150 Brussels (Belgium) – represented by Maarten G. Labberton
- EMPAC (European Metal Packaging Association), having its registered office at Av Louise 149/24, 1050 Brussels (Belgium) – represented by Guy Standaert
- EuPC (European Plastics Converters Association), having its registered office at Av De Cortenbergh 66, 1000 Brussels (Belgium) – represented by Geoffroy Tillieux
- EWF (European Wax Federation), having its registered office at Boulevard du Souverain 165, 1160 Brussels (Belgium) – represented by Alexandra Hadjiyianni
- FCA (Cefic Sector Group covering Food Contact Additives), having its registered office at Av van Nieuwenhuyse 4, 1160 Brussels (Belgium) – represented by Christian Jassogne
- Flexible Packaging Europe having its registered office at Am Bonneshof 5, 40474 Düsseldorf (Germany) – represented by Stefan Glimm
- Plastics*Europe* (Association of Plastics Manufacturers in Europe), having its registered office at Av van Nieuwenhuyse 4, 1160 Brussels (Belgium) – represented by Anne-Marie Hamelton. Under Plastics*Europe* rules, the Executive Director, Wilfried Haensel, signs this agreement.

Partner 05: Food Chemical Risk Analysis

Organisation:

Food Chemical Risk Analysis is the scientific consulting practice of Dr David Tennant. FCRA was established in 1998 and is built on his background as a senior scientist in UK government departments and experience with an international scientific consulting company. A key activity is the provision of consumer exposure analyses and risk assessments for food additives, nutrients, novel ingredients and other food and feed components using deterministic, distributional and probabilistic models. Other important activities include the European registration of animal feed additives, supervision of efficacy and safety studies, regulatory support on novel foods and novel food ingredients and surveys of food additive usage. David Tennant co-authored and edited the book 'Food Chemical Risk Analysis'.

Role in the project:

David Tennant has unique experience of dealing directly with food ingredient and additive manufacturers to estimate dietary intakes. His experience includes new substances with no precedence for human exposure, existing additives intended for use in foods and adventitious contaminants not intended to be present. He has coordinative responsibility for WP7 and will contribute to WPs 3 and 5.

Scientific/technical team and its experience in relation to the project:

David Tennant has been providing European food ingredient companies and trade organisations with bespoke food chemical intake estimates for use in regulatory decision-making for more than 10 years. Numerous intake models for food additives, novel food ingredients, food contact migrants and other food constituents have been reviewed and accepted by national, European (SCF, EFSA DGSANCO) and international (JECFA) food safety regulatory authorities.

Partner 06. French Food Safety Agency, Maisons-Alfort, FR (AFSSA)

Organisation/laboratory:

The French Food Safety Agency is responsible for risk assessment in the field of Food Safety in France but also for surveillance and research in this field. The Direction for Risk Assessment (DERNS) produces advices with the help of ten expert panels, among them the expert panel for Food additives and flavouring substances AAAT and the Food Contact Materials panel MCDA. In this Direction for Risk Assessment, the research and technical assistance unit PASER (20 scientists, mainly epidemiologists, biologists, statisticians, engineers in food science) is in charge of quantitative exposure and risk assessment and organises the National Dietary Surveys INCA in France. This unit is in charge of the monitoring of intake for food additives in France and will be strongly involved in FACET.

Role in the project:

Workpackage leader for WP 3 food additives, participation to WP 5 and to WP6

Scientific/technical team and its experience in relation to the project:

Dr. Jean-Charles Leblanc, principal scientific staff member involved in this project, is a Dipl. Biologist. He is active in the field of exposure assessment to contaminants and food additives for more than 10 years. He manages the team in charge of exposure assessment at Afssa/PASER. He manages the French Total Diet Study (TDS) surveillance survey of food additives and contaminants in France. He is member of the EFSA AFC Panel and WHO JECFA where he contributes to exposure assessments to food additives. He also participates in the FAO-WHO GEMS-Food surveillance program network and helps developing countries to develop food surveillance programs like TDS.

Dr. Jean-Luc Volatier is a Dipl. statistician specialized in sampling methods, head of PASER unit at Afssa. He is working in the field of dietary surveys and exposure assessment for 15 years. He participated in the former EU SCOOP tasks 4.1 and 4.2 on food additive intake surveillance and worked for AFSSA food additives panel during 3 years. He is responsible of the French National Dietary Survey program INCA. He was responsible for the statistical working group of the DG SANCO founded project EFCOSUM in 2002 on dietary survey methods. He is participating to 6th RTD projects EUROFIR (food composition) and EFCOVAL (food consumption).

Dr. Nawel Bemrah is a Dipl Veterinarian with a PhD in epidemiology. She is responsible for the food additives intake monitoring for France at Afssa since 2002. She has already participated in an EU research project (MED-VET-NET).

A scientist (engineer in agronomy/food science) will be recruited to work full time on the project.

Another scientist (master in food science) will be recruited to organize the surveys in France for food chemical occurrence (WP6) and levels of food additives data (WP3)

Partner 07. National Institute for Food and Nutrition Research, Rome, (INRAN)

Organisation/laboratory:

The National Institute for Food and Nutrition Research (INRAN) is a public research organisation within the Italian Ministry of Agricultural Policy and Forestry. Two INRAN research groups will be involved in FACET. The "Food Organoleptic Quality" research group has experience and expertise in food quality evaluation studies, approaching the issue by both analytical instrumental methods and sensory procedures. The laboratory is supplied with instrumental systems for GC-MS and HPLC analysis and for the measurement of physical properties of foods. The laboratory also has adequate sensory booth facilities and a trained panel. The "Food safety - exposure analysis" research group has expertise in the exposure assessment of food chemicals present in the diet. It is currently involved in the following EU projects: CASCADE (VIFP, http://www.cascadenet.org), NOFORISK (VIFP www.noforisk.org), EFCOVAL (VIFP http://www.efcoval.eu/) and HELENA (VIFP http://www.helenastudy.com/). This research group is the Italian contact point of the European Food Safety Authority within the food consumption database manager's network.

Role in the project:

INRAN will lead the WP Flavourings and will be involved in the WP Consumption, WP Modelling and WP Occurrence.

Scientific/technical team and its experience in relation to the project: **"Food safety – exposure analysis" research group**: Catherine Leclercq, Dr (F) – principal scientific staff member involved in this project, leader of the research group, nutritionist and expert of exposure assessment to food chemicals, expert in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) since 2002 and in a Panel of the European Food Safety Authority (EFSA) since 2003. Marika Ferrari (F) – researcher, biologist, involved in research related to public health nutrition. Stefania Sette (F) – Senior Dietician, manager of the INRAN food consumption database. Raffaela Piccinelli, (F) – nutritionist, manager of INRAN databanks used in food consumption surveys. Cinzia Le Donne, (F)- nutritionist, involved in the design and carrying out of food surveys. Giovina Catasta (F) - Senior Dietician, highly qualified in the analysis of consumption data, Elisabetta Toti (F) Senior Dietician, highly qualified in the analysis of consumption data. Pasquale Buonocore (M) Early Dietician, experience in field survey and preparation of databases.

"Food Organoleptic Quality" research group: *Flavio Paoletti*, (M) – experienced researcher, food chemist. *Antonio Raffo*, (M) – early Researcher, food chemist. *Nicoletta Nardo*, (F) – Experienced laboratory technician.

Partner 08 Technical University Munich, Freising-Weihenstephan, DE (TUM)

Organisation/laboratory:

The Chair of General Food Technology belongs to the Department Food and Nutrition of the Food and Life Science Center of the Technical University Munich (TUM) in Freising-Weihenstephan, Germany. Research focuses on the application of analytical methods to the assessment of food quality and safety. The techniques established range from metabolite profiling (GC-MS) of crops to the analysis of minor lipids (LC-GC-MS). In particular, the group has long and extensive experience in the investigation of volatile constituents occurring in fruits and vegetables. The laboratory is equipped with modern instrumentation for analytical and sensory analyses of flavouring substances. Major expertise has been built up regarding the capillary gas chromatographic separation of enantiomers using chiral stationary

phases (MDGC), the analysis of sulphur-containing trace constituents and the application of enzymes to kinetic resolutions of chiral aroma compounds.

Role in the project:

TUM will be involved in the Flavourings WP. Main responsibilities will be the selection of representative flavouring substances and the establishment of analytical data on flavouring substances in foods.

Scientific/technical team and its experience in relation to the project:

Prof. Dr. Karl-Heinz Engel, principal scientific staff member involved in this project, is a food chemist by education. He has been involved in research on aroma compounds in foods for more than two decades. He has also extensive experience regarding the regulatory assessment of foods and food ingredients. He has been chair of the Working Group "Flavourings" of the Scientific Committee on Food of the European Commission and holds this position presently in the AFC Panel of EFSA. He has contributed with his broad analytical expertise to several EU projects (SAFOTEST, ENTRANSFOOD, NOFORISK, and SAFEFOODS).

Mrs. Julia Poplacean, Technical Assistant*,* highly qualified in the analysis of aroma compounds.

N.N., food chemist to be nominated.

Partner 09: FABES GmbH, Munich, DE (FABES)

The organisation:

FABES Ltd. is a private R&D company founded in 1997 by Dr. O. Piringer. The expertise of FABES is the investigation of mass transfer from various types of materials into contact media, the theoretical modelling of migration and development of user friendly software for migration modelling. The main field of activity is the investigation of migration from packaging into foods and food simulants. The company owns state of the art analytical equipments and develops expert theoretical models and software for migration simulations. At FABES Dr. Peter Mercea leads the group which develops software for migration modelling and uses these tools for evaluation/interpretation of experimental migration data.

Role in the project:

Coordinative responsibility for WP4.2d - development of models for the migration from multi layer/multi materials into foods and their use to calculate from the data produced in WP4.2c the migration parameters needed for the exposure estimations.

Scientific/technical team and its experience in relation to the project:

Dr. O. Piringer - dipl. chemist - since 1997 leader of FABES before, for about 20 years, head of department at the Fraunhofer-Institute for Process Engineering and Packaging (FHG-IVV). Coordinator of the STM4-CT98-7513 project - scientific foundation for implementing in Article 8 of the Plastics Directive 2002/72/EC the modelling of migration. Actively involved in the EU-projects "Certified Reference Materials" - Contract G6RD-CT2000-00411, FoodMigrosure - Contract QLK1-CT2002-2390 and Migresives- Contract COLL-CT-2006-030309. Active as national expert to EU Commission DG Sanco and the German "Plastics Commission'. As (co)author - more than 100 scientific publications in the food packaging area.

Dr. Peter Mercea – dipl. physicist - since 1997 contract scientist for FABES Ltd., - develops modelling tools (including software) for "mass transfer phenomena" and "interaction between packaging and foodstuffs". Involved as expert in the STM4-CT98-7513 project. Before 1997 working for 20 years in research institutions from Romania, Russia, USA and Germany in the field of substance separation with membranes and mass transfer from packaging materials.

Mrs. Anja Zülch – dipl. chemist - highly qualified in analytical chemistry, coordinated activities of FABES in the framework of the FoodMigrosure - project.

Partner 10: Fraunhofer IVV, Freising, DE (FHG IVV)

***Organisation/laboratory*:** The Fraunhofer Institut für Verfahrenstechnik und Verpackung (Fraunhofer-Institute for Process Engineering and Packaging) in Freising, Germany, is one of the 50 institutes of the Fraunhofer-Gesellschaft (FHG) which is an organisation for applied research and development. FHG IVV consists of several scientific/technical departments, one of them being the Dept. 'Product safety & chemical analysis' with a major focus on ‚Food Packaging Migration and Safety' and headed by Dr. Roland Franz . In his group, there exists large experience in the broad research field of interactions between foodstuffs and packaging materials and related compliance testing and analytical work. The laboratory which is sufficiently equipped with modern analytical instrumentation according to the latest state of technology is accredited according to DIN EN ISO/IEC 17025:2005 on migration testing and with more than 50 analytical methods in the area of food packaging safety.

***Role in the project*:** Coordinative responsibility for large parts in sub WP4.2. Responsible for WP4.2-a (new classification of foods) and WP4.2-c (experimental studies on multi–layer/material parameters)

Scientific/technical team and its experience in relation to the project: Dr. Roland Franz, principal scientific staff member involved in this project, by education being Dipl. chemist, he is since 1987 active in the field food - packaging interactions. Large experience concerning industry projects, but also close involvement in regulatory affairs. Active as national or personal expert to EU Commission (DG Sanco, DG Research) and the German national health authorities as member of BfR's well-known ‚Plastics Commission'. Member of CEN TC 194/SC1 (General chemical methods of test for food contact materials) and it's working groups. Large experience in coordination of EU projects was/is initiator and coordinator of several successful EU projects such as the recently finalised EU project QLK1-CT2002-2390 'FOODMIGROSURE'. He is (co)author of more than 100 scientific publications in the food packaging area. Dr. Angela Störmer, Food chemist, research scientist, since 1997 active in the field of food contact materials. Was coordinator of an important EU project (G6RD-CT2000-00411) and currently co-managing the EU project COLL-CT-2006-030309 'MIGRESIVES'. Dr. Jan Ungewiss, Dipl-chemist, highly qualified in analytical chemistry. Mrs. Anita Gruner, Mrs. Ruth Wildgruber are lab technicians and a PhD student will be recruited.

Partner number 11. Nutrition Unit, Department of Health Promotion and Chronic Disease Prevention, National Public Health Institute (KTL), Helsinki, Finland

Organisation:

KTL (National Public Health Institute of Finland) is a state research institute led by Director General, Prof., MD Pekka Puska. The institute is engaged e.g. in epidemiological, nutritional, biochemical, immunological, genetic, toxicological, and microbiological research areas related to public health. The personnel are about 900. The Nutrition Unit (headed by Professor Pirjo Pietinen) is the main unit in KTL responsible for the nutrition research and development of methods of food consumption and nutrient intake. The Unit studies the associations between dietary factors and the risk of chronic diseases. The Nutrition Unit is responsible for the National Dietary Survey, the FINDIET Study, carried out every fifth year. The Unit also maintains the National Food Composition Database Fineli® (http://www.fineli.fi). The Nutrition Unit is also active in nutritional risk assessment.

Role in the project:

Partner 11 will participate and contribute and to the WP5, WP6, WP7.1, and WP8 of the project. The Nutrition Unit is able to provide the project the food consumption data from the FINDIET 2007 Study. In the study 2054 persons were interviewed using the 48-h recall method. Half of the participants were additionally asked to fill in a 3-day food record twice (the first starting the day after 48-h recall in early

spring, and the second in June-September). About 930 participants (about 91%) returned the first 3-day food record and about 60% both 3-day food records. The other half of the participants were asked to fill in a product diary in which all foods purchased to the household or to be used by the participant only (sweets, soft drinks etc.) were recorded in a 5-day diary. For each food item, the generic name, the brand name, number of items purchased, package size, and five last digits of the EAN code were recorded. The response rate of that part of the data collection was 90%.

Scientific team and its experience in relation to the project:

Dr. Liisa M. Valsta, Ph.D. (Human Nutrition), M.Sc. (Food Science and Technology/Food Toxicology), Principal investigator of the Partner 11 in this project, Senior researcher in the Nutrition Unit at the National Public Health Institute (KTL). Main research interests in the area of food composition/quality of diet, metabolic responses and health. In addition she has long experience in methodological and practical aspects of monitoring diet and nutritional status, nutritional risk assessment, and developing food databases in national and in international collaborative projects. Dr. Valsta will be in charge of coordinating and organizing the tasks of this project in Finland.

Professor Pirjo Pietinen, D.Sc. (Human Nutrition), Head of the Nutrition Unit and Chair of the Nutritional Risk Assessment Project.

M.Sc. Heli Reinivuo is nutritionist and manager of the National Food Composition Database Fineli®, involved also in carrying out and analyses of food surveys.

M.Sc. Harri Sinkko is the statistician in the Nutritional Risk Assessment Project. Experienced in deterministic and probabilistic intake estimation of both nutrients and contaminants.

M.Sc. Heli Tapanainen is the statistician in the FINDIET Study. Experienced in deterministic and probabilistic intake estimation of dietary intake.

Partner 12. STFI-Packforsk AB, Stockholm, SE (STFI.PF)

The organisation/laboratory:

STFI-Packforsk is one of the world's leading R&D companies in the fields of pulp, paper, graphic media, packaging and logistics. The activities range from basic research to direct assignments along three value chains: packaging, graphic media and bio-based energy and chemicals. The combined competence, from material science to consumer value, is utilised to find solutions applicable at the customers. The group's annual turnover is 290 MSEK and the number of employees is 280. STFI-Packforsk is located in Stockholm and Örnsköldsvik, in Kristinehamn through its subsidiary company Lignoboost AB and in Trondheim, Norway, through its subsidiary company PFI AS.

Role in the project:

Participant in WP 4.1 Design and compile a database of occurrence data, giving quantitative information on the substances used in the different packaging materials. Investigation and identification of food contact layer for food packaging materials collected in EU member countries, choice of food packaging for migration modelling.

Scientific/technical team and its experience in relation to the project:

MSc.P.Eng, Kristina Salmén principal scientific staff member involved in this project,
by education from Royal Institute of Technology, Stockholm, 1978. Project leader of both EU projects and industry projects on migration from packaging to food. Member of different industry groups in EU, FCA at CEFIC, CEN/TC194/SC1 and it working groups, chairwoman of CEN/TC194 /SC1/WG2 responsible for the development of analytical methods for monomers and additives according to EEC regulations. 25 years' experience from the area legislation and migration from packaging materials for foods. Responsible for the development of the STFI.PF Database - Health Shopping Basket for food packaging.

MSc.Ch.Eng, Beatrice Buzsaky Johansson, project manager for the Swedish Shopping Basket. A study that follows the packaging development for everyday commodities in Sweden during a succession of years and where a number of key-figures have been used. Project manager for a research project about consumer behaviour.

Ph.D, Mikael Gällstedt: Renewable barrier materials for packaging. Senior Research Associate at STFI.PF. He is (co) author of more than 100 scientific publications in the packaging areas of; Fundamental research and polymer analysis; Packaging plastics and barrier films; Polymer barrier composites for packaging,

MSc.Ch.Eng Marianne Björklund Jansson. Chemical analysis of pulp and paper, and product safety issues for different food contact materials. Technical leader of accredited chemical analysis.

Partner 13: Central Food Research Institute (CFRI)

Organisation/laboratory

CFRI was established in 1959 in order to carry out research and development in the field of the food industry, as well as to provide food regulation data. One of the main objectives of CFRI research is to contribute to the safety operation of food producers and to the identification of the food safety risk factors of in the entire food chain. CFRI provides research on biochemical and nutrition-physiological relations of food components from the point of view of modern, healthy nutrition. CFRI develops new analytical methods especially considering the requirements of food control and traceability. It provides social and economic analysis regarding food safety. CFRI develops cooperation with industrial companies, governmental, social organisations and the consumers.

Role in the project:

Taking part in the following activities of WP 5, WP 6 and WP7.1: collecting information and statistical data regarding food input of the Hungarian population and population groups, completion of food frequency questionnaires, establishment of a foodstuff composition database by fixing label information and participation in the development of the food consumption modelling system.

Scientific/technical team and its experience in relation to the project

Prof. Dr. Diána Bánáti is the Director General of CFRI. She is professor of Corvinus University of Budapest and has a PhD in food safety. She is a qualified expert in food safety, food policy and food regulatory sciences; she has a wide research experience in food science. Her current focus is the EU harmonization, food safety communication and consumer perceptions. Her management activities include strategic planning and management of R&D projects. She is a member of several international organisations among others in the Management Board of European Food Safety Authority (EFSA).

Dr. Erzsébet Szabó has a PhD in food economy. Her primary research areas are food marketing, consumer habits and behaviour.

Annamária Tóth is researcher of CFRI and a PhD student. Her scientific interests are consumer behaviour, novel foods and food ethics.

Viktória Szűcs is researcher of CFRI and going to be a PhD student from the autumn of 2008. Her scientific interests are food additives, food safety assessment, and decision making of consumers.

As an integral part of the food safety research tasks at the Food Economy and Quality Unit, questionnaire assessments are made at different food chain players (agricultural producers, food processors, food trade, restaurants and public catering) as well as at the certain vulnerable consumers and consumer groups (e.g. pregnant women, coeliac, diabetic and elderly people). CFRI's investigations were extended by research on consumers' nutritional habits to utilise these results in product development and marketing communication. The above mentioned Unit is experienced in numerous methods (like questionnaire surveys, focus group and in-depth interviews) and different

types of analysis and has many statistical software (e.g.: SPSS15.0, HLM6, MecAnalyst, PolyAnalist, Atlas ti., QSR NVivo).

Partner 15. CREMe Software Ltd., Innovation Centre, Trinity College, Dublin 2, Ireland (CREMe)

Organisation/laboratory:

CREMe Software ltd. is an Irish SME created to further develop the research results generated over more than 6 years of research in Trinity College Dublin in the area of probabilistic modelling of population exposure to food borne chemicals. Since the company was formed, the team has continued to perform research in the area of probabilistic models and population exposure including the following projects:

- Colipa (www.colipa.com) funded Modelling and Exposure Assessment of European Population to 7 Cosmetics products. (Food Additives & Contaminants, 2007, (45)2086-2096; 2097-2108)
- FSAI Salt Reduction model development in the Irish population. 2006 (to be published)

For more information, please see www.cremesoftware.com.

Role in the project:

Coordination, research and development of exposure modelling software tool. This involves working on development of deterministic and probabilistic exposure tools for the three key areas of food safety (additives, flavourings and packaging migrants). CREMe will also be involved in WP 5 regional diet modelling in developing the algorithms and tools for modelling diets in areas where there is a lack of detailed food consumption data.

Scientific/technical team and its experience in relation to the project:

Cronan McNamara (MSc), Mr. McNamara has worked in the area of probabilistic exposure assessments in Trinity College Dublin. Managing and developing the software tool in the EU FP5 Monte Carlo (http://montecarlo.tchpc.tcd.ie/) , later in the Enterprise Ireland funded CREME Project (http://www.tchpc.tcd.ie/research/cprojects/creme.php, 2003-2006) and later in the EU FP6 NOFORISK (www.noforisk.org) project. Mr. McNamara founded CREMe Software Ltd. to use the intellectual property from Trinity College to bring an exposure assessment tool to groups around Europe and farther a field.

David Rohan (MSc), Mr. Rohan has been involved in the EU FP5 Monte Carlo project in Trinity College as a probabilistic modelling expert and software development. He also worked on the CREME and NOFORISK projects developing specific exposure assessment models and tools for different areas of food safety. Mt. Rohan was also a founding member of CREMe Software.

Dr. Edel Duffy is a consultant and advisor to CREMe Software and is a leading expert in the area of Food Packaging exposure assessment.

In summary, principal researchers and founders of CREMe have been involved in the research and scientific development of the following projects in Trinity College:

- EU FP5 Monte Carlo Project – probabilistic modelling of food chemicals: additives, pesticides, and nutrients. 1999-2003 (http://montecarlo.tchpc.tcd.ie/)
- Enterprise Ireland CREME Project in packaging exposure assessment models. 2003-2005 (http://www.tchpc.tcd.ie/research/cprojects/creme.php)
- EU FP6 NOFORISK Project into novel food ingredient exposure assessment. 2003-2007 (www.noforisk.org)

Partner 16: Universidad de Santiago de Compostela, Santiago de Compostela, ES (USC)

The organisation/laboratory:

The University of Santiago de Compostela was founded in 1495. At present USC has 19 Faculties, 75 Departments and a staff of 3,000 (> 2000 are professors and researches).The Laboratory of the participant research group is located at the Faculty of Pharmacy and it is fully equipped with all necessary analytical instrumentation for the execution of the tasks of the proposed project. Since 1990 the research group has been working in Food Contact Materials subject and it has a large experience developing analytical methods for migrants in foods, food simulants and residual starting substances in packaging materials, carrying out overall and specific migration tests and determining key parameters of diffusion (diffusion coefficients, partition coefficients, etc.).

Role in the project:

Responsible for WP4.2-b (A_F concept for foods (diffusion properties) and participation in WP4.2-a (new classification of foods) and WP4.2-c (experim. studies on multi–layer/material parameters).

Scientific/technical team and its experience in relation to the project:
P. Paseiro , principal scientific staff member involved in this project, is Doctor ”Cum Laude” of Pharmacy (1980), Full time Titular Professor (1984) of the Department of Analytical Chemistry, Nutrition and Bromatology at Faculty of Pharmacy. He has directed 17 Doctoral Thesis, 14 national projects and has more than 100 scientific papers and he has participated in 4 EU projects [“Development of methods of analysis for monomers … (MAT1-CT92-0006), ACTIPAK (PL 98-4170), RECYCLABILITY (PL 98-4318) and FOODMIGROSURE, (QLK1-CT2002-02390)]. He also has participated in the “Ad hoc group on coatings” (Committee of experts on material coming into to contact with food) of the Council of Europe and he is member of the “Working group on Food Contact materials” to help to Scientific Committee of AESAN (Agencia Española de Seguridad Alimentaria y Nutrición).
Dr. Cruz, is a senior research incorporated to the USC two year ago trough the prestigious “Ramón y Cajal” Programme, funded by the Spanish Government to lure back young scientists working abroad and boost Spain’s ailing research system. Dr. Cruz has participated in more than 10 national and international projects related with food additives and natural antioxidants and he has published 35 research papers in SCI journals.
A junior research and Lab technician to be nominated.

Partner 17. National Food and Nutrition Institute (IZZ), Warsaw, Poland

Organisation

The National Food and Nutrition Institute was established as an independent scientific and research institution by Resolution of the Council of Ministers of 12 April 1963, in consultation with FAO and with its financial support.

Major achievements of the Institute during its nearly 45-year-long history include:

- development and popularisation of Dietary Reference Intakes, as well as tables of food composition and nutritional value,
- researches of diets and nutritional status of the population of Poland,
- co-operation with international organisations, including:
    a) the World Health Organization (WHO) - WHO Collaborating Centre for Nutrition, WHO Collaborating Centre for Food Contamination Monitoring, a member of the WHO “nutrition counterparts” network,
    b) the Food and Agriculture Organisation (FAO) - FAO Focal Point for ICN,
- participation in the preparation of Poland for the EU accession as regards adjusting Polish food law,
- participation in carrying out international projects, in particular in the EU framework programmes,

- establishment of the reference laboratory performing food tests within the scope of nutrients and selected food safety parameters,
- prevention and treatment of overweight and obesity and of other non-communicable chronic diseases associated with improper diet,
- development of handbooks intended for doctors, dieticians and patients in the *Instytut Żywności i Żywienia zaleca* (National Food and Nutrition Institute recommends) series,
- publication of the *Żywienie Człowieka i Metabolizm* (Polish Journal of Human Nutrition and Metabolism) quarterly and the *Prace IŻŻ* (Works of the NFNI) series,
- Educational and consultative activities.

The Institute, authorised by the Minister of Health, is responsible for implementing in Poland the WHO Global Strategy on Diet, Physical Activity and Health through the National Prevention Programme for Overweight, Obesity and Non-communicable Chronic Diseases through Diet and Improved Physical Activity (2007-2016).

Role in the project:

Contribution in WP 5, WP 6, WP 7.1

Scientific/technical team and its experience in relation to the project

Professor Mirosław Jarosz - Director of the National Food and Nutrition Institute. In 2004 he was appointed professor in medicine by way of decision of the President of the Republic of Poland. He has been carrying out clinical activities associated with internal diseases, gastroenterology and nutritional therapy. The main areas of his scientific research include epidemiology, etiopathogenesis, diagnostics, and therapy of diet-related diseases of the alimentary tract, malignant neoplasm in particular. Also, he carries out research on interaction between food, food supplements and drugs, as well as on the influence of nutritional therapy on the effectiveness of hospital treatment.
His works include 220 publications, which appeared both in Poland and abroad. He led and/or cooperated in implementation of 16 research projects sponsored by the World Bank, the Ministry of Science and Information Technology, and the European Union, as well as 30 projects carried out as part of the statutory activity of the National Food and Nutrition Institute. As the national counterpart he cooperates in the area of food, nutrition and diet-related diseases prevention with the WHO Regional Office for Europe.

Dr. Iwona Traczyk - Doctor of Human Nutrition and Food Technology. She is the Deputy Director for Scientific Research and Head of Laboratory of Nutritional Health Risk Factors in the National Food and Nutrition Institute in Warsaw. She has research experience in human nutrition, public health and food safety. She took part in the legislative work concerning Polish food regulations. She has been actively involved in the survey concerning estimation of food additives intake by Polish population. Currently her main research interests are food allergy and genetically modified food. She is an author of over 80 publications on food safety and human nutrition. She is a member of Polish Scientific Nutrition Society and the Research Council in the National Food and Nutrition Institute. She was the leader of WP2 “Diet” in the Chemical Food Safety Network for the enlarging Europe (SAFEFOODNET).
M.Sc. Alicja Walkiewicz - Master of Science of Human Nutrition. She has worked as research assistant in the National Food and Nutrition Institute. She has cooperated in works setting Polish regulations in the area of food safety. She has been actively involved in the survey concerning estimation of food additives intake with diets by Polish population. Her professional and scientific activity is also participation in the risk assessment concerning fortified food.

Partner 18: National Institute for Research and Development of Isotopic and Molecular Technologies (INCDTIM) Cluj-Napoca, Romania, *www.itim-cj.ro*

The organisation/laboratory:

Founded in 1950, certified as National Institute in 1999, INCDTIM is structured in four research laboratories and a prototype workshop. The main research domains focus on molecular and biomolecular physics, stable isotope applications in biology, development of analytical tools (mass spectrometry, gas chromatography and NMR in particular) for environmental applications, pharmaco-kinetics studies, transport phenomena through biological membranes.

Role in the project: Responsible for WP4.2e Probabilistic modelling of concentration of FCM constituents in packed foods. Link to Exposure modelling WP8.

Scientific/technical team and its experience in relation to the project:

Dr. Valer Tosa, as Senior Research Scientist, is the leader of a numerical modeling group in his home institute, working in the field of molecular physics. He spent long periods of time in research teams in Europe (Napoli University, Garching Max Planck Institute for Quantum Optics), Japan (RIKEN, Wako-shi), and Koreea (KAIST, Daejeon), demonstrating his capability to collaborate and work in different academic and research environments.

In the last few years he approached as the main direction of research computer modeling of various physical and chemical phenomena based on numerical techniques of solving differential equations. He built computer programs for the calculation of *i)* heat diffusion in photopyroelectric multilayered materials, *ii)* infrared multiphoton absorption of polyatomic molecules, *iii)* ultrasort pulse propagation in ionizing gas media, *iv)* gas permeation through polymeric membranes, *v)* diffusion of impurities in polymeric multilayer systems.

Due to his substantial experience in numerically solving differential equations, he recently started developing a model for substance migration in and from multilayer polymer structures; with application in migration estimation in food packaging. He designed the physico-chemical method and the corresponding numerical algorithm, based of finite differences, to solve the parabolic type equation of diffusion for the case of a multilayer system having different diffusion and partition coefficients.

The results he obtained constantly attest his abilities for a thorough analysis and understanding the physical and chemical phenomena in the field of atomic and molecular physics, a solid expertise of the numerical methods, excellent programming skills and competence to analyse, predict and explain the experimental results. He published more than 75 articles in international peer reviewed journals.

Partner 19. Confederation des Industries Agro Alimentaire (CIAA) Belgium

Organisation/Laboratory

CIAA membership is made up of:

* 25 National Federations, including 2 observers;
* 30 EU sector associations;
* 20 major food and drink companies grouped in a Liaison Committee.

CIAA's permanent secretariat, based in Brussels, is a major contact partner of/partner in consultations with the European and international institutions on food-related developments. It co-ordinates the work of more than 500 experts, grouped together in Committees and Expert Groups around the following three themes: Food and Consumer Policy, Trade and Competitiveness and the Environment. Through these Committees and Expert Groups, manufacturers from all EU countries provide broad and in-depth expertise. They contribute to establishing CIAA positions on key issues which, once approved, are then communicated to European and international decision makers. CIAA co-operates with other organisations and associations such as ILSI, EUFIC, International Alliance of Food Producers Associations – IAFPA, UNICE, FEBC, AIM (www.ciaa.eu)

Role in the project

CIAA and its Scientific Expert Group will work with industry sectors in the area of food additives to provide anonymised data on typical ranges of use levels of food additives in the foods belonging to the food category identified by the food additives group. CIAA will have a participant in the latter workpackage

Scientific/technical team and its experience in relation to the project

Beate Kettlitz, food chemist by training, as Director Food Policy, Science and R&D, being directly involved in both recent publications as mentioned below will coordinate together with Mike Knowles the chairman of the CIAA Science expert group the CIAA contribution to the project. Virginie Rimbert, nutritionist by training, Manager - ETP Secretariat / Food Policy, Science and R&D, will support the CIAA contribution.

Partner 20. RCC Ltd, Itingen/Basel, CH (RCC)

No longer in the project

Partner 21 JRC (Joint Research Centre), Ispra, IT (DG JRC IHCP)

Organisation/laboratory:

The Physical and Chemical Exposure Unit of the Institute for Health and Consumer Protection of the European Commission Joint Research Centre is strongly anchored in exposure assessment underpinned by strong laboratory activities. The activity on Food Contact Materials (FCM) within the PCE Unit is firmly established, led by Dr. Catherine Simoneau, with more than 10 years of recognised expertise, >10 staff and >400 m2 of dedicated laboratories and offices. It acts as scientific and technical support to the Commission, in particular DG SANCO. Research have included monitoring of target contaminants at the European level, interaction between food and migrants, exposure assessment, method development and harmonisation, participation in EU projects, dissemination of results. It has become the Community Reference Laboratory for Food Contact Materials in the Regulation of Official Feed and Food Controls EC/882/2004, and holds an accreditation EN ISO/IEC 17025. The activity has also a very strong emphasis on consultation, networking, training and capacity building, knowledge sharing and public service. Examples include major conferences for EU projects, chairing of task forces/workshops, courses (e.g. migration modelling), laboratory training, web-sites, EU databases for substances, and communication.

Role in the project:

Participation in WP4.2; and 4.1; Support WP8.1 and WP8.2

Scientific/technical team and its experience in relation to the project:

Dr Catherine Simoneau, Head of the Sector FCM and Director of the CRL-FCM. She has implemented and been in charge of the field of FCM at JRC exclusively since 1995. She is a food chemist with extensive experience in food science, nutrition, chemical engineering, food toxicology, and analytical chemistry. She is active at the regulatory level (DG SANCO, DG RTD), in risk assessment (EFSA), as well as in metrology and CEN (member/chair in TC194 SC1 WGs). Experience in EU projects including coordination of workpackages, and unique expertise in organising major events for stakeholders.

Dr. Barbara Raffael, Industrial chemist, research scientist, since 2002 active in the field of food contact materials. Was involved in the Recyclabilty project.

Mr. Sandro Valzacchi, Chemist, highly qualified in analytical chemistry.

a post- doctorant to be nominated

Partner 22. FCNAUP

Organisation/laboratory:

The "Faculdade de Ciências da Nutrição e Alimentação da Universidade do Porto (FCNAUP)" (Faculty of Nutrition and Food Sciences of University of Porto), headed by Professor Maria Daniel Vaz de Almeida, is one of the 14 Faculties of the University of Porto which is the largest University in Portugal. FCNAUP is the only state Faculty in Portugal awarding the 'Licenciatura' (bachelor) degree course in Nutrition, and has been undertaking high quality research activities, namely in public health nutrition. Several projects in FCNAUP include teaching staff from other Faculties or Universities (national and international), providing more laboratories and/or financed projects possibilities.

Role in the project:

Our group will contribute to WP6, chemical occurrence through a targeted food ingredient survey, to WP 5 by gathering data on local food intake surveys and through targeted small food frequency questionnaires and then to WP 7 through assistance with regional modeling via local expertise

Scientific/technical team and its experience in relation to the project:
Pedro Moreira, nutritionist, PhD in Human Nutrition (2001), is Vice-President of Scientific Board and Vice-President of Directive Board of FCNAUP, and Associate Professor in Human Nutrition (since 2002), and Member of the "Advisory Group on Food Quality and Safety", European Comission (2005-2006). He is (co)author of several publications about food intake in children and adults.

B2,2,1 List of work-package (WP) leaders

WP no.	WP Leader (Beneficiary no)	Beneficiary short name
1	01	UCD
2	07	INRAN
3	06	AFSSA
4	03	CSL
5	02	UU
6	01	UCD
7	05	FCRA
8	15	CREME
9	19	CIAA
10	01	UCD

B.2.3 Consortium as a whole

A consortium of this nature, representing researchers and stakeholders with extensive experience in food chemical exposure assessment has never before been put together in an EU Framework Programme in exposure assessment. CIAA as a participant, through its many EU and National Food Sector Groups gives FACET a unique access to the manufacturing food sector. In addition, the involvement of a consortium of 14 food packaging material companies who are investing €400,000 in real cash into FACET is again unprecedented. The project is very fortunate in having the EU's own Joint Research Centre (JRC). JRC is a major technical organ of the EU Commission which has direct access to 27 member states National research Laboratories as well as others in EEA AFTA countries. The packaging section of JRC (CRL-FCM) has direct collaborative links with EFSA too and can tap into methods of analysis from petitioners (directly in EFSA intranet) for dissemination into the public domain. Therefore they can provide up-to-date methods of analysis which are rendered anonymous by CRL-FCM for migrants that might be considered in the project. JRC-FCM has a strong institutional

mission foothold in exposure assessment and will sustain the legacy of the FACET project beyond its completion. An example in a closely related area has been the integration of the legacy of the EU project EXPOFACTS into a JRC led website. CRL-FCM has a strong commitment to dissemination of results and has a proven track record of organising major events related to FCM: examples include the ILSI-JRC joint workshop on exposure assessment which set some first benchmark to the development of further work in the area. Other significant examples include the final symposium of the EU project "Recyclability" which attracted close to 130 participants, and the closing conference of the "foodmigrosure" project which attracted close to 150 participants. Besides large companies, FACET also has a total of four SME's (participants 5, 9, 12 & 15) involved in the project representing 22.8% of the budget.

In terms of experience in food regulatory affairs, almost all of the research partners either are or were involved in EU Food Regulatory Affairs. Panel members of EFSA include

Name	**Partner**	**EFSA Group**
Catherine Leclercq	INRAN	AFC Panel
Karl Heinz Engel	TUM	AFC Panel
Laurence Castle	CSL	AFC Panel
Jean Charles LeBlanc	AFSSA	AFC Panel
Diana Banati	CFRI	EFSA Council

The consortium is rich in research scientists who have published extensively in the field of food chemical exposure, and who in the past have had limited exchanges regarding the problems and opportunities in this area. The present consortium mixes experts in all elements of food chemical exposure in a matrix of expertise, which has never been done before.

There are two final points to be made about the "consortium as a whole". The first is a deliberate attempt to capture as diverse a geographic mix as possible and we have achieved a north-south-east-west and central linkage. The consortium had wished to have all 27 member states involved but this became financially impossible, therefore the project will focus on regions representing the diversity of the EU. Secondly, the consortium delivers into Framework 7 the accumulated experience of comparable efforts in FP5 and FP6 (MonteCarlo, Migrosure, Noforisk projects). Thirdly, from a financial point of view, with a budget of €5.8m and 20 partners, the consortium is competitively priced. In conclusion, FACET brings together a major multidisciplinary, multi-sectoral group to deliver high quality science to an important societal issue and to do so in a way which is sustainable beyond the project.

B2.3.1 Sub-contracting

The project will receive assistance in a small but specialized task to recalculate and recalibrate QSAR equations and software to improve their predictive capabilities; €40k has been allocated to sub-contract-out this work.

B.2.4 Resources to be committed

Due to the diverse team of partners and the vast experience of all organizations in the areas of additives, flavourings and packaging materials, there are a wealth of resources that are to be committed to the project. These include:

1. Expert personnel, many of whom have experience in working and/or coordinating other Framework projects, and also some of whom sit on EFSA expert panels (refer to section B2.3

for full description of consortium). Industry involvement in relation to the additives work-package (CIAA) and in relation to the packaging work-package (CEPE - representing the packaging industry). Members of CEPE are not going to use EC funds for their role in the project, but all their expenses are to be in-kind contributions.

2. Dietary databases: Many of our partners have experience in collecting and analysing dietary databases, and also have access to these data. These databases include the Irish national dietary surveys of Adults (1997-1999), Children (2003-2004) and Teenagers (2005-2006), INFID (Irish national food & ingredient database), Italian database of consumption, Italian database of composition of food supplements available on the Italian market, national Italian dietary survey database 2005-2006 (infants, children, teenagers, adults and elderly), Finnish national dietary surveys (2007), Italian ingredient database of standard recipes, Finnish database on recipes, food composition, units of consumption and composition of supplements, Hungarian panel on surveys and eating habits (approx €2000), Hungarian household budget survey reports (2005), Hungarian food composition tables (2005), Polish household food consumption and anthropometric survey (2000), expertise in creating, analysing and conducting surveys using food frequency questionnaires (FFQs) and access to the UK NDNS surveys.
3. Computer software and state-of-the art equipment including: CREMe online database management system (as a tool for data collection storage), the CSL model, hardware and software for developing the module concerning the probabilistic model development, knowledge and expertise in food chemical exposure analysis, databases, software and techniques
4. Packaging data: STFI data from CEFIC FCA project, CEPE coating inventory list, EUPIA generic list, PIRA report exposure paper and board, Migresive adhesive under progress, knowledge and experience gained form the Foodmigrosure project, expert knowledge on migration measurements from food contact materials in contact with foodstuffs and specialised migration cells to be used for this purpose, EU Community reference laboratory databases on chemicals/substances (substances and physicochemical characterisation), EU Community reference laboratory database on methods of analysis, Irish national food packaging database (children and adolescents).
5. Other: JRC will bring to the project their expertise in dissemination of data from other projects (recyclability, foodmigrosure, CRL-FCM), JRC and CRL-FCM networks, expertise in maintaining legacy of data from other projects(Expofacts, EIS CHEM-risks, Heimsta).

B3. Potential impact

B.3.1 Strategic impact

The European Food Safety Authority (EFSA) is an independent agency charged with risk assessment in relation to food. The European Commission and within that, DG SANCO is responsible for risk management. Both bodies are actively involved in exposure assessment. Presently there are a number of bottlenecks in the knowledge pipeline for exposure assessment. These include poor central access to national food consumption databases, difficulty in re-structuring food categories to match the needs of food chemical exposure, little or no knowledge on the occurrence of permitted chemicals in foods, a dearth of data on food chemical concentration and a complete lack of data which would allow exposure estimates to packaging substances. FACET will attempt to fill all of these voids and will create a surveillance system which is sustainable beyond the project. The impact of this new exposure landscape 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 present study provides 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, 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.

B.3.2Plan for the use and dissemination of foreground

B.3.2.1 Exploitation of project results. A number of routes of communication will be used:

- **Website:** The project will create a website which will be maintained by the coordinator. Each WP leader will provide a six-monthly one page on (a) research achievements and (b) forthcoming tasks and these will be posted on the website. All presentations at the annual plenary meetings and other meetings where appropriate will also be uploaded onto the website
- **Annual stakeholders meeting:** In years 2, 3 and 4, the coordinator will organize a meeting either in Brussels (EC) or in Parma (EFSA), to which interested scientists, Commission officials, EFSA, industry, the consumer organizations and some media will be invited. In this respect we will draw on the experience of the DG Research Joint Research Centre who has a considerable track record in this area.
- **Meeting with EFSA Expert Group on Food Consumption Data**: The coordinator is a member of this expert group and having presented on the FACET project to this group during the contract negotiation phase, we are committed to making a presentation at all of their meetings and we also expect to seek considerable advice on occasions from this group

- **Software**: In order to ensure continuity after the finish of the proposal, those partners (CSL, CRÈME, 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 (partner 21). The software tool will be freely available at the end of the project, either as a download-able program or on a CD. The European-wide database developed during the project will also be available as a download or on a CD.
- **e-Newsletter:** It is intended to develop an e-Newsletter for distribution twice per year with as wide a dissemination route as possible
- **Printed flyer:** It is intended to develop a printed flyer and appropriate stationery for distribution to the partners and the commission
- **Linkages:** Two Framework 7 projects have been identified which have synergies with FACET. These are NAFISPACK and FOCUS-BALKANS. The coordinator of the present project will invite these consortia to send a representative to the Plenary Research Group meetings.

B3.2.2 List of databases and modeling tools that will be developed in FACET

WP No.	**Database**	**S&T objectives (p.7)**	**Leading partner**	**Other partners involved**	**Milestone (MS) & deliverable (D)**
2.1	Concentration levels for representative flavouring substances	2	INRAN	TUM	MS 12 D2.1
4.1.1	Chemical substances used to make different packaging materials	1	STFI	CSL, CEPE	MS 13 D4.1.1
4.1.3 & 4.1.4	Database linking foods and food groups with different packaging materials and substances	1	CEPE	UU, CSL, STFI	MS 27 D4.1.1 D4.1.3
4.2.4	Database on diffusion & partition constraints for reference purposes *Compiled from WP4.2.1-4.2.3*	3	FABES	CEPE, INCDTIM, USC	MS 19
5	Harmonised database on nationally available food intake data in 8 EU member states. *Will be compiled from existing databases & FFQs on targeted food groups*	4	UU	UCD, AFSSA, INRAN, KTL, FCNAUP, IZZ, CFRI, CEPE	MS 14 MS 22 MS 26 D5.1
6	Database of targeted food chemicals occurrence in foods in 8 EU member states	1	UCD	UU, AFSSA, INRAN, KTL, FCNAUP, IZZ, CFRI, CEPE	MS 23 D6.1
7.2	Extend databases compiled in WP5 for regional modelling and for risk assessment procedures	5	FCRA	CSL, CRÈME, CEPE	MS 18 MS 20 MS 25 MS 26 D7.2
9	Database on technological use and range of concentration of food additives in targeted foods	2	CIAA	AFSSA, UCD	MS 24 D9.1

WP No.	Models/Tools	S&T objectives (p.7)	Leading partner	Other partners involved	Milestone (MS) & deliverable (D)
4.2.4	Migration model for multi-layer packaging	3	FABES	CEPE, INCDTIM, USC	MS 19 MS 21 D4.2.1
4.3	QSAR tool to estimate toxicity of food contact substances	3	CSL	CEPE, JRC	MS 11 D4.3
7.1	Develop a model for estimating European consumption of defined food groups	4	FCRA	CRÈME, CSL, CEPE, KTL, IZZ, CFRI, FCNAUP, UU	MS 26 D7.1
8.1	Develop models and provide a tool (PC-delivered software) for estimating exposure to additives, flavours and packaging materials *Integrate data from WP2,3,4,5,6 & 7*	5, 6	CREMe	CSL, CEPE, FABES, JRC, KTL, INRAN, AFSSA, UCD, JRC	MS 27 D8.1.2

B4. Ethical issues

Any studies which will involve humans will require ethical approval in each participating centre.

ETHICAL ISSUES TABLE		PAGE
Informed Consent		
· Does the proposal involve children?	**No**	
· Does the proposal involve patients or persons not able to give consent?	**No**	
· Does the proposal involve adult healthy volunteers?	**No**	
· Does the proposal involve Human Genetic Material?	**No**	
· Does the proposal involve Human biological samples?	**No**	
- Does the proposal involve Human data collection?	**Yes**	**37**
Research on Human embryo/foetus		
· Does the proposal involve Human Embryos?	**No**	
· Does the proposal involve Human Foetal Tissue /Cells?	**No**	
· Does the proposal involve Human Embryonic Stem Cells?	**No**	
Privacy		
· Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)	**No**	
· Does the proposal involve tracking the location or observation of people?	**No**	
Research on Animals		
Does the proposal involve research on animals?	**No**	
Are those animals transgenic small laboratory animals?	**No**	
Are those animals transgenic farm animals?	**No**	
Are those animals cloned farm animals?	**No**	
· Are those animals nonhuman primates?	**No**	
Research Involving Developing Countries		
· Use of local resources (genetic, animal, plant etc)	**No**	
· Benefit to local community (capacity building i.e. access to healthcare,	**No**	

education etc)		
Dual Use		
· Research having direct military application	**No**	
· Research having the potential for terrorist abuse	**No**	
ICT Implants		
· Does the proposal involve clinical trials of ICT implants?	**No**	
I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL	**No**	

B5. Consideration of gender aspects

FACET has 20 partners of which 57% are male and 43% are female. It is axiomatic that any reliable exposure databases and modeling tools MUST take full account of regional differences and any influence of age, gender and any factor that might drive exposure to high levels. Both genders will be included fully and equally in all food consumption databases as separate entries and in any other surveys conducted by FACET, both genders will be equally included. In considering minority groups, attention will also be paid to gender balance whether this is children of a specific age group or ethnic minorities.

Logical Framework for FACET

Table 1 – Overall Objectives

Overall objective	**Protection of the European consumer by increasing food safety**				
Project purpose	**Creation of a food chemical exposure surveillance system**				
Specific objective (from Technical Annex section B1.1)	**Deliverables**	**Intervention logic**	**Objectively verifiable indicators**	**Source of verification**	**Assumptions**
Record occurrence levels of targeted chemicals (additives, flavours & packaging migrants) in representative regions of the EU *(S&T objective 1)*	D2.2 D4.1.1 D4.1.2 D6.1	Concerted action to estimate occurrence for the 3 types of chemicals in food in the EU	A database of the occurrence of the target chemicals in foods	Results generated in WP 2.2, 4.1 & 6 Data inputs and data lists on occurrence from using the database	Occurrence data on all of the relevant food groups for each of the 3 target chemical types can be collected in representative regions of the EU
Targeted food chemical concentrations in food compiled in a database *(S&T objective 2)*	D2.1 D3.1 D3.2 D4.1.3 D9.1	Safety evaluation of target food chemicals is made possible by knowing the actual occurrence and concentrations	A database of targeted food chemicals have been developed, comprising information on food additives, food flavouring and food contact material concentrations.	Results generated in WP 2.1, 3.1, 3.2, 4.1 & 9 Source code, data inputs, data lists from using the database	The data providers outside of the project provide the necessary data and the database is established as foreseen.

Development of migration model of food contact material into food *(S&T objective 3)*	D4.2.1 D4.2.2 D4.3	A new in silico QSAR approach will be used to evaluate the toxicological significance of exposure to packaging substances.	A migration modelling framework for complex packaging materials into food, under real conditions of use, is available.	Results generated in WP 4.2 & 4.3 Source code, data inputs, data from using the modelling framework	The possibility to establish the framework by full functionality of the different component and introduction of a QSAR concept.
Tiered food intake database developed *(S&T objective 4)*	D5.1 D5.2 D5.3 D7.1	Food intake needs to be structured according to the food categories of importance for the food chemical intake.	The database exists and is populated with the food categories of importance for the food chemical intake.	Results generated in WP 5 & 7.1 Source code, data inputs, data lists from using the database	The relevant food categories can be identified. The data on food intake and food chemical occurrence/ concentration is compatible.
Database on national food consumptions set up *(S&T objective 5)*	D7.2.1 D7.2.2 D8.1.1 D8.1.2	A centralized and harmonised database on food intake reflecting different regions of Europe structured in a suitable way meets the needs of the exposure assessments.	Food consumption for the different regions of Europe is generated by using the database.	Results generated in WP 7.2 & 8.1 Source code, data inputs, data lists from using the database	The data available can be supplied with new information from FFQs.

To estimate exposure assessment using a probabilistic model. *(S&T objective 6)*	D2.3 D3.4 D8.1.3 D8.2.1	Development of software tool/model to estimate exposure to additives, flavourings and food packaging substances.	Consumer exposure to targeted chemicals in foods can be assessed using the tool developed. The tool is freely available and downloadable from the Internet.	Results generated in WP 2.3, 3.4, 8.1 & 8.2 Validation reports from the tool, down-load from Internet available	The creations of the components of the tool can be established and applied as envisaged. A web-based host is agreed for the tool.

Logical Framework Table 2 for all Work-packages

Logical Framework for WP1 (UCD)

Work-package objective	Tasks	Effort* (PM)	Expenses**	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
1. Establish and sustain effective technical coordination and project management	**1.1** To manage the organisational structures of FACET	UCD=22	*UCD = €113.3k*	Project management including communication between work-packages and timely decisions on project management issues.	Minutes of meetings and notes of meetings of the Project Plenary Group, the External Advisory Committee, the Project Executive and also meetings with the Commission and third parties. Attendance lists (available to partners) and the Management report.	Assumption: That the coordinator and the partners agree on the way to manage and coordinate the project. That decisions are taken in a timely fashion. Risk: That conflict occurs between project partners and that decisions and deliverables are not met according to the project schedule. Contingency: If the management of the organisational structures is not sufficient to sustain the project efficiently, then the coordinator should reinforce the management structures.
	1.2 To oversee reporting to the Commission	UCD=17	*UCD = €87.6k*	Reports delivered from the consortium to the Commission at the requested time-points	Individual contributions from partners.	Assumption: That all parties cooperate to provide the necessary documents on time to the coordinator. Risk: Parties do not cooperate with appropriate reporting procedures Contingency: If reporting/auditing is insufficiently performed by any

						of the partners, then payments could be postponed until the reporting obligation is fulfilled.
	1.3 Obtain ethical approval letters from all partners	UCD=1	*UCD = €5.2k*	Ethical approval letters obtained (Del. 1.1)	Ethical approval letters are from relevant bodies	Assumption: That all letters of ethical approval are received from the relevant bodies. Risk: Not all ethical letters are obtained. Contingency: Relevant partners are experienced in obtaining ethical approval. However if ethical approval in one centre cannot be obtained the workload will be shifted to the other centres that have obtained it.

*Total Person Months (PM) allocated to task, **Estimated costs for salaries. Amounts in kEuro, 1 million Euro ~ 1000 kEuro,

Logical Framework for WP 2

Work-package objective	**Tasks**	**Effort* (PM)**	**Expenses****	**Specific results produced Deliverables/ Contractual obligations**	**Sources of verification**	**Assumptions/Risks**
2.1 To develop a database of concentration levels for a set of flavouring substances that represent the 2,700 currently on the market	**2.1.1** Assignment of the approximately 2700 flavouring substances currently on the market into homogeneous categories according to potential toxicity, pattern of use, sensory characteristics and natural occurrence in foods	TUM = 3 INRAN =1 **Tot=4**	*TUM = €13.4k* *INRAN = €4.6k*	Flavouring substances classified with respect to the margin between safety limit and estimated dietary exposure, pattern of use, sensory characteristics and natural occurrence in foods at significant concentration level. Information retrieved from the opinions of scientific authorities such as Council of Europe,	A database with the 2700 flavouring substances assigned to homogeneous categories	Assumption: data are available for all flavourings substances. Risk: For some flavouring substances the information reported in the opinions of scientific authorities is not complete Contingency: Expert judgment from TUM will allow to assign flavouring substances to the appropriate categories

				EFSA and JECFA		
	2.1.2 Selection of representative flavouring substances (target flavourings)	TUM = 3 INRAN =1 **Tot=4**	*TUM = €13.4k* *INRAN = €4.6k*	Target flavouring substances selected from the homogeneous categories in order to represent all the conditions based on current methodological difficulties in the assessment of exposure; priority given to those flavourings present in products consumed by children.	A report with the list of selected flavouring substances and the selection criteria adopted	Assumptions: expert judgment from TUM allows selection of representative flavouring substances. Risk: expert judgment by TUM may not be sufficient to cover all categories of flavourings identified. Contingency: where needed, advice from flavouring industry will be searched
	2.1.3. Development of a database of concentration levels of target flavouring substances organized according to food descriptors used in food consumption databases	TUM = 3 INRAN =14 **Tot=17**	*TUM = €13.4k* *INRAN = €64.2k*	Database filled by making use of all available sources of information, in particular data provided by EFFA and IOFI to Council of Europe, SCF, EFSA and DG SANCO.	A report with reported concentration levels of target flavouring substances in food organized according to food descriptors used in food consumption databases	Assumption: concentration data made available by flavouring industry to the Council of Europe, to EFSA and to JECFA will be obtained and will allow to fill in the database. Risk: these data may not be sufficient to fill the whole database. Contingency: Specific analytical determination may be performed with the aim of filling the blanks, in addition to the analytical determinations performed in task 4
	2.1.4. Analytical determinations of target flavouring substances in products available on the market in order to assess the uncertainty in	TUM = 14 INRAN =18	*TUM = €62.7k* *INRAN = €82.5k*	Foods selected to cover representative uses of flavouring substances, with emphasis on products consumed by children, uncertainty of	Documentation of analytical determinations A report on the assessment of	Assumption: the selection of specific flavourings in specific food matrices will provide a good representation of the products containing flavourings available on the market

	occurrence data collected through food labels and in reported concentration data	**Tot=32**		occurrence and concentration levels assessed through analytical determinations in products available on the market (Del. 2.1).	uncertainty of occurrence and concentration data based on analytical data	Risk: there may be such a high variability in the uncertainty that 1000 analytical determinations may not be sufficient to provide a food representation of the uncertainty Contingency: In this case, worst cases and best cases will be selected to provide an overview of the range of possible cases
2.2 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.	**2.2.1.** Selection of processed food products to be included in the "Occurrence survey" to make possible the collection of information related to the presence of target flavourings	TUM = 3 INRAN =10 **Tot=13**	*TUM = €13.4k* *INRAN = €45.8k*	Food products and categories selected in order to make possible the collection of information related to the presence of flavourings in processed foods.	List of data on food products and categories that were selected	Assumption: INRAN and TUM have a good knowledge of the EU market of processed foods, of the relevant information present on food packaging and of the processed products that may contain flavourings. Risk: the guidance document developed by INRAN and TUM may not be fully adequate for the situation of other countries Contingency: Based on feed back from partners, a second adapted version of the guidance document will be distributed
	2.2.2. Development of a food categorization system allowing the use of food consumption databases for the assessment of exposure to flavouring substances	INRAN =8 UU = 1 **Tot=9**	*INRAN = €36.7k* *UU=€5k*	Categorization system harmonized for the eight EU Member States involved in WP5 developed, in terms of food coding, recipe break up, etc. (Del. 2.2)	Report describing the categorization of food products in the food consumption databases, in relation to flavouring substances.	Assumption: the initial food consumption data are codified at a sufficient disaggregation level in all countries involved. Risk: in some countries, the food consumption data are not disaggregated at sufficient level and will not provide information on the probability of presence/absence of flavourings.

						Contingency: where needed, food categories will be disaggregated based on theoretical assumptions related to the percentage of food products in each food category.
	2.2.3. Guidance to the development of exposure models to flavouring substances	TUM = 2 INRAN =13 UCD=1 **Tot=16**	*TUM = €9k* *INRAN = €59.6k* *UCD = €4.4k*	Guidance document on the information for the development of models of dietary exposure to flavouring substances. This will be provided on the basis of food consumption data categorized according to the system created for flavouring substances in Task 2, with special consideration given to the dietary exposure of high consumers of products susceptible to contain flavouring substances at relatively high concentration levels. (D2.3)	The information and data that was used to create the guidance document	Assumption: partners with expertise in patterns of consumption of foods containing flavourings (INRAN and TUM) will be able to provide to CREMe (the partner that will develop the models of dietary exposure) all the necessary input. Risk: it may be difficult for CREMe to develop an adequate model without having in–house expertise on the dietary exposure to flavourings Contingency: additional ad hoc meetings could be organized between INRAN, TUM and CREMe if increased collaboration is needed.

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Logical Framework for WP 3.1

Work-package objective	Tasks	Effort* (PM)	Expenses**	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
3.1 To propose a methodology for the codification of the national dietary surveys appropriate for EU exposure assessment to food additives	**3.1.1**. Constitution of a list of food categories for food additives	Afssa = 3 FCRA= 1 CIAA=1 UCD=1 **Tot=6**	Afssa = €14.7k *FCRA = €5.3k* *CIAA = €5.9k* *UCD = €4.4k*	List of food categories constituted from EU directives and GSFA New food classification of DG SANCO should be included	A database of food categories linked to food additive maximum levels will be delivered Minutes of the first WP3.1 meeting, of the meetings with DGSANCO and of the project plenary group.	Assumption: The basis of this task is the GSFA and the 3 EU directives. This task should include if possible the new EU classification for the new regulation. But this new classification should be available at the end of 2008. Risk: The new EU codification for food additives will not be available. Contingency: The list of food categories will only take into account current EU directives and GSFA. An update will be made when the new EU directive is available.

	3.1.2. Assessment of difficulties to interpret the content and limits of food categories	Afssa= 2 FCRA= 1 **Tot=3**	*Afssa = €9.8k* *FCRA = €5.3k*	Interview of the different users (risk assessors, national authorities and industrials)	A summary report of the users interviews will be provided	Assumption: Relevant users will agree to be interviewed, and that they will provide the requested information Risk: The requested information may not be provided, or the answers of the users may relate to the food classification of the EU directive of 2008. Contingency: Recalls to be organized to increase the response rate or second round of interviews to be done
	3.1.3. Description of food categories with examples of foods included and excluded	Afssa=2	*Afssa = €9.8k*	Description of each food category with the help of DG SANCO and national authorities	The update of the food categories database with examples will be delivered Minutes of meeting with DG Sanco	Assumption: DG SANCO and national authorities will help with description of food categories. Risk: DG SANCO and national authorities will not help with this task or there is a delay in accessing relevant information Contingency: Other sources of information will be used such as European databases or classification already available. Use the results of the interviews of 3.1.2

	3.1.4. Criteria for the selection of available dietary surveys for exposure assessment	Afssa=2	Afssa = €9.8k	Evaluation of dietary surveys available in Europe A summary report on the codification systems available for food additives in a selection of national dietary surveys will be provided (Del 3.1)	Answers of national dietary survey managers, description of the codification of some available dietary surveys (France, Ireland, Italy).	Assumption: National dietary survey can be translated in the new codification Risk: The new codification does not match with any national dietary survey Contingency: Introduce food additives classification in Epic-soft (Efcoval – EU project)
	3.1.5. Procedures to define food categories corresponding to food additives categorization systems	Afssa=3	*Afssa = €14.7k*	Tables of links between dietary surveys codification systems and food additives categories in EU regulation	A report on procedures will be delivered Recommendations on the management of food products and their ingredients in the dietary surveys will be provided	Assumption: Existing links between national dietary surveys and food additives categories Risks: Some food categories of the national dietary surveys don't match with any category in the EU regulation for food additives Contingency : Work with the national dietary surveys Managers to make the food categories precised or redefined in the national dietary surveys

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Logical Framework for WP 3.2

Work-package objective	Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
3.2 To provide a list of high priority food additives to be studied for exposure assessment	**3.2.1**. Introduction of occurrence information and food intake in the food categories-food additives database	Afssa = 3 UU=1 UCD=1 **Tot=5**	*Afssa = €14.7k* *UU = €5k* *UCD = €4.4k*	Frequency of use by additive and food category provided This information should be introduced in the food categories – food additives database	List of the most frequently used food additives.	Assumption: Intermediate Information from WP6 should be available for a selection of countries in order to be able to classify food additives according to occurrences Risk: No information available from WP6 Contingency : Use of information already available (tier 1, 2 and for some countries tier 3 of the evaluation of food additives intake in Europe)
	3.2.2. Definition of high priority food additives by using different sources of information	Afssa= 3 FCRA=2 **Tot=5**	*Afssa = €14.7k* *FCRA = €10.7k*	Ratios of TMDI/ADI by food additive for a selection of countries Scientific publications and reports (Del. 3.2)	Comparison of the TMDI/ADI ratios with other already existing data (tier 2 of DG Sanco food additives intake monitoring)	Assumption: Access to mean intakes in national dietary surveys should be possible (France (Afssa survey), Ireland (UCD survey) and Italy (INRAN survey) Risk: Surveys are already available. The main risk is the change of EU regulation. Contingency: Use of the maximum limits of the actual regulation and not of the next one

	3.2.3. Collection of production levels from the industry	Afssa=3 CIAA=3 **Tot=6**	*Afssa = €14.7k* *CIAA = €17.6k*	Figures of production levels for Europe and eventually of use levels by the industry	Answers to the questionnaires sent to the food additive industry	Assumption: Precise answers obtained from the food industry Risk: No answers or information about occurrence but without any values. Contingency: Recalls to increase the answer rate and the pertinence of response.

Logical Framework for WP 3.3

Work-package objective	**Tasks**	**Effort* (PM)**	**Expenses ****	**Specific results produced Deliverables/ Contractual obligations**	**Sources of verification**	**Assumptions/Risks**
3.3 To collect information on real usage levels for the high priority food additives defined previously	**3.3.1**. Elaboration of a questionnaire on real usage levels for the high priority food additives defined previously	Afssa = 3 CIAA=3 **Tot=6**	*Afssa = €14.7k* *CIAA = €17.6k*	Questionnaire elaborated according to priority food additives an food categories The type of information needed on ranges of real usage levels will be precisely defined in order to be able to perform an exposure assessment in the next subtask.	Questionnaire on real usage levels to be sent to industry members	Assumption: The list of high priority additives provided by WP 3.2 and the list used for the questionnaire elaborated in cooperation with DG Sanco-CIAA match Risk: There is a difference between the list from WP 3.2 and the one used in the questionnaire, due to new additives authorizations between the last evaluation (tier1,2 and 3 – 1997) and Facet Contingency: Work with occurrence data or information given by experts for the new authorized additives.

	3.3.2. Sampling plan and sampling frame for the survey on real usage levels	Afssa = 3 CIAA = 3 **Tot=6**	*Afssa = €14.7k* *CIAA = €17.6k*	Methodology for industry members sampling for the survey on usage levels. Statistical description of enterprises and food sectors from EU countries to be interviewed by CIAA (WP9)	Statistical report on the description of industry members (by country, size of the firm…). Methodological report on sampling.	Assumption: Selected industry members accept to participate Risk: Responding industry members are not representative Contingency: Complementary selection to be done.
	3.3.3. Pilot study on real usage levels to prepare the task 9.2.1	Afssa = 3 CIAA = 3 **Tot=6**	*Afssa = €14.7k* *CIAA = €17.6k*	Questionnaires will be sent. Answers of the industry participants analyzed	Results of the pilot survey (self-declared ranges of real usage levels)	Assumption: The response rate will be correct Risk: Low response rate will be the main risk Contingency: recalls will be organized to increase the response rate
	3.3.4. External validation of WP 9	Afssa = 6 CIAA = 3 **Tot=6**	*Afssa = €14.7k* *CIAA = €17.6k*	Food technology experts consulted on the usual ranges of use levels Comparison of the survey results on use levels with scientific publications	Summary report of the consultation and the comparison Identification of food additives and food categories with a too low response rate for future research	Assumption: Identification of experts. EFSA and national authority expert panel lists will be used. Risk: low response rate, difficulties to identify the experts Contingency: ranges of real usage levels will be provided by bibliography and by the CIAA survey.

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Logical Framework for WP 3.4

Work-package objective	Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
3.4 To provide guidance to exposure assessment and to the development of dietary surveys to take into account the necessary information for food additives intake surveillance	**3.4.1**. Identification of parameters useful for exposure assessment to food additives	Afssa= 2 Creme=1 FCRA=1 **Tot=4**	*Afssa = €9.8k* *Crème = €4k* *FCRA = €5.3k*	Parameters of deterministic and probabilistic approaches discussed Identification of additional information (brand name for example)	Specifications of the chronic exposure assessment model to be used for food additives	Assumption: The identification of the parameters is clearly established Risk: Lack of information or incomplete data Contingency: Use other sources of information (cf. 3.4.2)
	3.4.2. Identification and test of other sources of information than dietary surveys (marketing panel data)	Afssa = 6	*Afssa = €29.5k*	Information on consumption frequencies like marketing panels or propensity /FFQ identified and tested for at least one country	Results on brand loyalty and day to day variation of intake for almost one country (France) Summary reports on additional studies on brand loyalty and survey duration	Assumption: Brand loyalty and day to day variation data are available from the marketing panels Risk: marketing panels don't provide the needed information Contingency: Probabilistic modeling approach, based on different assumptions (sensitivity analysis)

	3.4.3. Transmission of specifications for food additives exposure assessment	Afssa=4 Creme=1 UCD=1 FCRA=1 **Tot=7**	*Afssa = €19.7k* *Crème = €4k* *UCD = €4.4k* *FCRA = €5.3k*	Transmission of the specifications for food additives exposure assessment and datasets to the FACET exposure assessment work-package (Del 3.4)	Report on specifications for food additives exposure assessment	Assumption: Availability of parameters in dietary surveys and in the database on food additive range levels produced by WP3.3 Risk: limited information on real usage range levels provided by WP9 or limited information on occurrences provided by WP3 Contingency: use of data already available by other sources in some participating countries (Irish INFID database, Afssa survey on 13 food additives)

*Total Person Months (PM) allocated to task, **Estimated costs for salaries. Amounts in kEuro, 1 million Euro ~ 1000 kEuro

Logical Frameworks for WP 4

WP4.1:

Work-package objective	Overall Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
4.1 To obtain information on, the types of food, the packaging for the different foods and the chemical composition of food packaging materials in order to allow migration levels to be estimated and linked to food consumption data using the tools developed.	**4.1.1**. Compile a Packaging Substances Inventory List.	CSL=1 CEPE=6 STFI =2 JRC=1 **Tot=10**	*CSL= €5.2k* *CEPE^* *STFI = €15.4lk* *JRC=€5.2 k*	Knowledge of substances used in different packaging materials, presented in a consolidated list (Del 4.1.1)	Data sheets collected from industry	Assumption: Requires all industry members to submit data through an annonymising channel (i.e. trade associations). Risk: Any sector failing will not give a complete picture. Contingency: To prevent this from happening, a FACET Industry Group (FIG) has been formed. FIG is bound by a consortium agreement.
	4.1.2. Design and compile a database of occurrence data giving quantitative information on the substances used in the different packaging materials.	CSL=3 CEPE=6 STFI=5 **Tot=14**	*CSL= €15.6k* *CEPE^* *STFI = €38.5k*	A link made between substances in the inventory list, the packaging materials where they could possibly be present, and the concentration in the packaging materials.	A database submitted to other partners	Assumption: Similar to Task 1, this needs industry input. Risk: There is a risk that not all the quantitative data can be obtained. Contingency: Working assumptions will be made using analogous substances / functionalities to fill data gaps.

	4.1.3. Design and compile a database on the types and extent of use of different packaging materials using a food classification system that allows migration levels to be derived.	CSL=3 CEPE=15 STFI=4 **Tot=22**	*CSL= €15.6k* *CEPE^* *STFI = €30.8k*	A link made between packaging, foodstuffs in that packaging, substances in that packaging, and market penetration of packaging types. (Del 4.1.2)	A database submitted to other partners	Assumption: :the data are representative of the total EU packaged food market. Risk: The risk is that imported packaged food may contain a different range of substances or different packaging. Contingency: Food industry will confirm any differences in packaging type. Partner 12 will confirm experimentally the absence or presence of substances. Any differences will be incorporated into the uncertainty input parameters.
	4.1.4. Link substance occurrence to each food item / group / category consumed.	CSL=3 CEPE=12 STFI=2 **Tot=17**	*CSL= €15.6k* *CEPE^* *STFI = €15.4k*	Exposure estimates made for some substances for all of the packaging sectors involved (Del 4.1.3).	The exposure estimates and supporting documentation submitted to Project Stakeholder Group for critique.	Assumption : the model is reliable. Risk: Model will give misleading estimates if inaccurate input data or incorrect data links are made e.g. between dependent and/or independent variables. Contingency: The stakeholders will critique the output and recommend any more efficient or transparent ways to populate the databases, fill the data gaps, and estimate exposure.

	4.1.5. Extending the databases to represent all EU member states	CSL=6 CEPE=5 STFI=18 JRC=3 **Tot=32**	*CSL= €31.2k* *CEPE^* *STFI= €138.4k* *JRC=€15. 6k*	Packaging information for the 100 market leaders in 5 countries. Experimental data on ca 3,000 food packages collected from at least 12 EU countries.	A report submitted for evaluation by other partners.	Assumption : that samples are representative. Risk: There is a risk that too few samples or unrepresentative samples may be collected. Contingency: WP4 partners will compile detailed sampling instructions. Project co-ordinator and relevant partners in the consortium will reinforce the importance of collecting the required number of samples.

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WP4.2:

Work-package objective	Overall Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
4.2 To establish a verified publicly available PC based 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	**4.2.1**. New classification of foods/food groups based on solubility properties (log $P_{O/W}$ versus $K_{P/F}$ studies)	CSL=7 CEPE=1 FABES=0.5 FHG=33 USC=5 JRC=10 **Tot=56.5**	*CSL= €36.4k* *CEPE^* *FABES = €4.9k* *FHG = €145.2k* *USC = €9.7k* *JRC = €52k*	A new food classification system based on thermodynamic properties and guidance how to use it. Definition of approx. 30 food categories, 20 model migrants, and 3 representative food contact plastics as donors. Experimentally derived substance-food-donor partition coefficients. Information on the temperature dependency of $logP_{O/W}$.	Four separate reports will be issued to partners for expert review.	Assumption: is that the properties of all foods with respect to migration can be described by a few critical parameters leading to a limited set of representative food 'groups' (classifications). Risk: The main risk is that migration especially from non-plastic materials may not be described thus. Contingency: Although not ideal, the number of food groups would be increased to get an acceptable fit.

	4.2.2. Study of diffusion properties of foods /food groups concerning as a basis for a 'A_F concept' for foods	CSL=10 FABES=1 USC=31 JRC=12 **Tot=54**	*CSL= €52k* *FABES = €9.9k* *USC = €60.1k* *JRC=€62.4k*	Analytical methods identified and validated for kinetic migration studies. Kinetic migration data. Concentration profiles data.	Three separate reports will be issued compiling the data and their interpretation.	Assumption: that analytical methods are available already or can be developed within the resource available, to generate the large amount of experimental data needed. Risk: There is a risk that insufficient resource is allocated for method development and validation. Contingency: The substances selected will be partially based upon ease of analysis. The resource will be deployed to achieve a minimum body of data, starting with the easiest substances first.
	4.2.3. Experimental study on migration parameters in multi-layer/multi-material systems (reference partition coefficients)	FHG=16 FABES=2 USC=3 JRC=1 **Tot=22**	*FHG = €70.4k* *FABES = €19.8k* *USC = €5.8k* *JRC = €5.2k*	Reference values for partition coefficients between relevant materials applied for multi-layer / multi-material packaging structures	A report compiling the reference values.	Assumption: that the equilibrium position will be reached in reasonable time so that food spoilage will not occur and that a large number of experiments can be performed within the project timeframe. Risk: This may not be the case for all multi-layer materials studied. Contingency: To counter this possibility, lower molecular weight high diffusivity substances can be used along with food preservatives.

	4.2.4. Migration modelling for multi-layer/multi-material packaging in contact with foods – "$(D/K)_nD$ model'	CEPE=1 FABES=6 INCDTIM=2 USC=1 JRC=1 **Tot=11**	*CEPE^* *FABES = €59.3k* *INCDTIM = €5k* *USC = €1.9k* *JRC =€5.2k*	Software developed for deterministic migration modelling of multi-layer/multi-material packaging structures. Comprehensive data on diffusion and partition constants (D and K). (Del 4.2.1)	Software module available on CD. Compilation report of migration parameters.	Assumption: that current migration models for monolayer plastics can be modified. Risk: The risk is that multi-layer materials including non-plastics such as paper and adhesives will not be properly described by these models. Contingency: If so, alternative numerical solutions will be sought to describe the migration process.
	4.2.5. Probabilistic modelling of concentrations of FCM constituents in packed foods & link to exposure modelling in WP8	CSL=1 CEPE=1 FABES=3.5 FHG=1 INCDTIM=16 JRC=1 **Tot=23.5**	*CSL = €5.2k* *CEPE^* *FABES = €34.6k* *FHG = €4.4k* *INCDTIM =€40k* *JRC =€5.2k*	Probabilistic migration model for multi-layer/multi-material packaging structures, designed, tested and validated. Elucidation of the method for data communication with other modules of the exposure modelling. (Del 4.2.2)	Migration model module delivered to and implemented by WP8 partners	Assumption: that the migration model will be a module integrated into the final modelling tool. Risk: The risk is that the flux of data (questions asked, data out) will not pass between the different modules. Contingency: Specifications will be decided ahead of time to prevent this.

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WP4.3:

Work-package objective	Overall Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
4.3 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	**4.3.1**. A set of 200 FCS will be used with different QSAR programmes to compare predicted toxicity endpoints against published data	CSL=10 CEPE=4 JRC=0.5 **Tot=14.5**	*CSL= €35k* *CEPE^* *JRC = €2.6k*	The accuracy of predictions will be known, using established software package(s) applied to FCS with different toxicological endpoints.	A report allowing performance of the QSAR tool(s) to be judged against accuracy criteria decided in advance by the Project Stakeholders.	Assumption: It is assumed that there is a QSAR tool that is accurate. Risk: There is a risk that in order to have an acceptably low level of false negatives, the QSAR model will generate a high level of false positives. Contingency: Investigate alternative QSAR tools.
	4.3.2. The QSAR equations will be recalculated to improve the predictive capabilities and the improved model(s) revaluated	CSL=4 CEPE=2 JRC=0.5 **Tot=6.5**	*CSL= €14k* *CEPE^* *JRC=€2.6 k*	Improvement of the QSAR tool for the prediction of the toxicity of hitherto untested Food Contact Substances (Del 4.3)	A report allowing performance of the improved QSAR tool(s) to be judged against accuracy criteria decided in advance by the Project Stakeholders.	Assumption: QSAR predictions are improved when the equations are recalculated. Risk: Does not improve performance. Contingency: If full QSAR cannot be developed with acceptable performance then a simplified tiered level of thresholds based on structure classes will be proposed instead.

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Logical Framework for WP 5

Work-package objective	Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
5.1. To compile a publicly available, PC based database on food intake across 8 countries which are geographically representative regions of the EU (Ireland, UK, France, Italy, Portugal, Finland, Poland & Hungary) based on existing databases	**5.1.1**. Information on food consumption databases from these 8 regions collated.	UU=1	*UU = €5k*	Compilation of food consumption database information from the 8 representative EU regions (Del 5.1) Database of Food Consumption Data	Information from national databases	Assume data exist for each region Risk: Incompatibility of different data types, language barriers Contingency: Liaise with EFSA DATEX unit
	5.1.2. Analysis of methods of data collection, food grouping systems, linguistic definitions of food groups across EU databases	UU=3 INRAN= 3 AFFSA= 1.5 CEPE = 1 **Tot: 8.5**	*UU = €15k* *INRAN = €13.7k* *Afssa = €7.4k* *CEPE^*	Methods of data collection, food grouping systems, linguistic definitions of food groups across EU analysed (Del 5.2)	A harmonised detailed database giving hierarchal structure – food groups Guidelines for the appropriate use of this harmonised database	Assume data exist for each region Risk: Cultural dietary preferences, language barriers Contingency: Liaise with EFSA DATEX unit
5.2. Create new targeted food frequency questionnaires	**5.2.1**. Identify EU countries from the 8 representative regions which have limited food consumption data	UU=1	*UU = €5k*	From collated database on EU food consumption databases, identify countries that lack sufficient level of detail for exposure assessments	List of countries with limited food consumption data	Risk: that data from the representative regions are of sufficient quality to allow for exposure assessment. Contingency: Liaise with EFSA DATEX unit
	5.2.2. Create targeted FFQ's for specific EU countries where food consumption data limited. Liaise with WP 2, 3, 4, 6	UU=5 INRAN= 4 AFSSA=2	*UU = €25k* *INRAN = €18.3k*	FFQ's created to target specific food groups in countries identified in Task 5.3	FFQ	Assume that FFQ's created will be sensitive/specific enough to obtain sought information on targeted food groups in certain EU regions Risk: Language barriers

	& 7 to create FFQ's.	UCD=1 KTL=2.6 FCNA=2 IZZ=1 CFRI=1 **Tot: 18.6**	*Afssa = €9.8k* *UCD = €4.4k* *KTL = €10.6k* *FCNA = €4.6k* *IZZ = €1.4k* *CFRI = € 2.95k*			Contingency: Liaise with EFSA DATEX unit
	5.2.3. Administer targeted FFQ's in specific countries to specified number of people. Compilation of results	UU=13 INRAN =5 AFSSA=2.5 UCD=2 KTL=6 FCNA=5 IZZ=5 CFRI=5 **Tot: 43.5**	*UU = €65k* *INRAN = €22.9k* *Afssa = €12.3k* *UCD = €8.8k* *KTL = €24.4k* *FCNA = €11.5k*	FFQ's created in Task 5.4 administered in relevant EU countries. Results complied and entered into appropriate dietary analysis software. Intakes of targeted food groups calculated for all relevant EU countries (Del 5.3)	Minutes of meetings post data collection. Report of results of food group intakes	Assume representative sample chosen to complete FFQ's Assume FFQ's completed accurately and that respondents provide correct information Risk of shortcoming's of the FFQ method Contingency: Liaise with EFSA DATEX unit

			IZZ = :€7k *CFRI =* €7.66k			

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Logical Framework for WP 6

Work-package objective	**Tasks**	**Effort* (PM)**	**Expenses ****	**Specific results produced Deliverables/ Contractual obligations**	**Sources of verification**	**Assumptions/Risks**
6.1 To construct a publicly available, PC based database on the occurrence of selected food additives, food flavouring substances and food contact materials in representative regions of the EU	**6.1.1** Based on target food categories, 8 partners to purchase brands per food category based on market share. Packaging photographed and ingredients entered into food ingredient database. Packaging isolated and described	UCD= 26 INRAN = 10 AFSSA = 7 UU = 9 KTL= 12.6 FCNA= 11 IZZ = 10 CFRI=10	*UCD = €114k* *INRAN = €45.8k* *Afssa = €34.4k* *UU = €45k* *KTL= €51.3 k* *FCNA =*	Comprehensive food ingredient data collected from each of the 8 countries (Ireland, UK, France, Italy, Finland, Portugal, Poland and Hungary). Food packages collected for relevant foods Database of food ingredient data, (also containing information on occurrence of food additives, flavourings	National Data from 8 countries Digital library of all food packages collected created in each centre.	Assumption: the ability to collect relevant food ingredient data in each of the 8 countries. Risk: Food ingredient data for certain foods may be difficult or impossible to gather in certain countries. Contingency: Target food categories agreed on by all partners involved in this task prior to data collection.

		Tot: 96.6	*€14k* *CFRI = €13.96k* *CEPE^*	(Del 6.1)		
	6.1.2 Researchers trained to describe packaging materials. Sample of packaging retained	UCD = 2 INRAN = 2 AFSSA = 1 UU = 1 KTL= 2 FCNA= 2 IZZ = 2 CFRI=2 CEPE = 2 **Tot: 16**	*UCD: = €8.8k* *INRAN = €9.2k* *Afssa = €4.9k* *UU = €5k* *KTL = €8.1k* *FCNA = €4.6k* *IZZ = €2.8k* *CFRI = €5,95k* *CEPE^*	Researchers trained to recognise packaging materials by packaging experts. Food packaging samples retained in each centre	A training manual developed by packaging experts given to all researchers. Reference library of packaging samples in each centre	Assumption: the ability of packaging experts (WP4) to train researchers to recognise packaging materials. Risk: Researchers have not complete understanding of packaging materials and incorrectly classify them. Contingency: Classification of a proportion of the Reference library of packaging samples and digital photographs can be double checked by packaging experts.

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Logical Framework for WP7.

Work-package objective	Tasks	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
7.1. Collaborate with other WPs to develop suitable food grouping systems and a modelling framework for estimating consumption for the defined good groupings for all EU member states, and test the method with known data sets.	**7.1.1** Development of food grouping systems. **7.1.2** Model development **7.1.3** Method testing	FCRA = 6.5 Crème= 32 CSL = 23 FCNA = 8 IZZ = 6 CFRI= 6 KTL = 8.1 UU = 4 CEPE = 3 UCD = 2 **Tot: 98.6**	*FCRA = 34.6k* *CRÈME = €129k* *CSL = €92k* *FCNA = €18.4k* *IZZ = €8.4K* *CFRI = €15.76k* *KTL = €33k* *UU = €20k* *CEPE^* *UCD = €8.8k*	Food consumption data from EU countries with good data arranged by agreed food grouping system; Computer model to extrapolate to countries without data; Modelled data for countries without data (Del 7.1 & 7.2.1)	Reports on the success of using the model to predict food consumption patterns in EU countries the do not presently have national food consumption data.	Assumption: The Task is dependent on the other WPs being able to determine a suitable hierarchical food classification system and provide a suitable base-set of food consumption data. Risk: The lack of a suitable categorised base-set will make extrapolation of new national data sets impossible. Contingency: Surrogate data will be obtained directly from UK and Irish national databases. .

7.2. 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.	**7.2.1** Validation **7.2.2** Database development	FCRA = 5 Crème = 4 CSL = 7 CEPE = 1 **Tot: 17**	*FCRA = €26.6k* *CRÈME = €16.1k* *CSL = €28k* *CEPE^*	Validation of the national food consumption databases derived by extrapolation in Task 7.1. (Del 7.2.2) Deterministic and probabilistic models based on the national food consumption data obtained in Task 7.1.	Final report on the outputs of the model including a database of validated national European food consumption patterns and computerised modelling system for estimating intakes of food chemicals	Assumption: Final development of the model and database is dependent on successful validation using FFQ data. Risk: Validation of new datasets will not be possible without FFQ data. Contingency: Other sources of validation including direct contact with national representatives will be applied if the FFQ data are not available.

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Logical Framework for WP8

Work-package objective	Tasks	Original WP Task	Effort* (PM)	Expenses **	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
8.1 To develop practical yet innovative alternatives to the current simplistic and criticised first-tier exposure models in each area: flavourings (WP 2), additives (WP3), and packaging (WP 4) and to validate a methodology and construct a publicly available, PC based tool and data set that will allow robust food safety exposure assessments for the European population into the future.	**8.1.1** Initiate a discussion with expert groups and plenary group of member states.	8.1 t1, 8.2 t1, 8.2 t2	CREMe: 2 CSL: 1 CEPE: 1 INRAN: 1 KTL: 2 UCD: 0.5 AFSSA: 1 **Tot: 8.5**	*CREMe = €8.1k* *CSL = €4.0k* *CEPE^* *INRAN = €4.6k* *KTL = €8.1k* *UCD = €2.2k* *Afssa = €4.9k*	Understanding of the issues from all groups and stakeholders.	Minutes of meetings, draft document agreed by partners on recommendations	Assumption: that the group will be able to organise meetings with expert groups. Risk: that meetings are delayed or that key attendees will not be available to attend. Contingency: early notification of meetings and phone conference call systems if required.
	8.1.2 Development of expert elicitation algorithms	8.1 t2	CREMe: 12 CSL: 12 **Tot: 24**	*CREMe = €48.4k* *CSL = €48k*	Algorithms for expert elicitation for exposure models	Minutes of meetings and algorithm documentation.	Assumption: that the modelling team can work with the exposure experts to develop algorithms, Risk: that scientific difficulties or data limitations restrict progress. Contingency: staged process of development from simple to more complex models to ensure algorithms are delivered.
	8.1.3 Development	8.1 t3	FABES: 2	*FABES = €19.8k*	Algorithms and models for packaging migration	Minutes of meetings and	Assumption: that the modelling team can work with the exposure

	of exposure and packaging migration models				exposure models (Del 8.1.1)	model documentation.	experts to develop algorithms, Risk: that scientific difficulties or data limitations restrict progress. Contingency: staged process of development from simple to more complex models to ensure algorithms are delivered.
	8.1.4 Integration and refinement of model	8.1 t4	CREMe: 28 CSL: 1 CEPE: 1 **Tot: 30**	*CREMe = €112.9k* *CSL =€4.0k* *CEPE^*	Exposure Model prototype (Del 8.1.2)	Model prototype demonstration.	Assumption that the modelling partners deliver their elements of the model on time and that these elements can be combined. Risks: Delay in model elements from WP 8.3 and 8.4 and difficulty in combining model elements. Contingency: Seek assistance from the teams to ensure on time delivery and in combining the results. If necessary, seek assistance from the coordinator in ensuring project deadlines are met.
	8.1.5 validation of exposure models	8.1 t5	CREMe 16 CSL: 2 CEPE: 2 ~~UCD: 0.5~~ INRAN: 2 AFSSA: 2 KTL: 1.6	*CREMe = €64.5k* *CSL = €8.0k* *CEPE^* *UCD = €2.2k* *INRAN = €9.2k*	Exposure model validation	Model Validation Report	Assumption: that the modelling partners will work with the expert groups to validate the model. Risks: There are risks in communication between the groups and in project management. Contingency: Organisation of a ~~workshop and meeting in person~~ will be organised if required.

			Tot: 26.1	*8k* *KTL = €6.5k*			
	8.1.6 Investigate sustainability of model	8.1 t6	JRC: 7	*JRC = €36.4k*	Discussion of details of the sustainability of the model into the future	Minutes of meetings.	Assumption: that stakeholders will be identified who are interested in the sustainability of the model. Risks: Difficulty in organising discussions with stakeholders. Contingency: Seek assistance from the coordinator and other relevant partners in the consortium to organise the group if required.
	8.1.7 Model validation of report of refined models	8.1 t7	CREMe: 2 CSL: 2 CEPE: 1 **Tot: 5**	*CREMe = :€8.1k* *CSL =€8.0k* *CEPE^*	Final model validation (Del 8.1.3)	Report and meeting minutes and discussion.	Assumption: that the partners will work together to validate the model. Risks: Lack of data, lack of organisation and difficulty in validating the model. Contingency: Meetings will be organised to share data and to discuss difficulties in validating the model.
8.2 To provide an online system for data collection and collaboration. To work with food experts in WP 2, 3, 4 and the data generated in the project. To validate and refine the models developed	**8.2.1** Provision of web based data management system	8.2 t3	CREMe: 8	*CREMe = €32.3k*	Web based data management system	Access to the data system for partners	Assumption: that participant 15 can provide a user friendly data management tool for partners to define and share data. Risks: Technical difficulties in delivering the system and user difficulties in using the system to gather data. Contingency: Technical difficulties will be addressed by partner 15 and will address any end user difficulties through online training

							or a workshop if required.
	8.2.2 Provision of software and performance of exposure assessments	8.2 t4	CREMe: 12 CSL: 3 CEPE: 1 **Tot: 16**	*CREMe = €48.4k* *CSL =€12k* *CEPE*^	Exposure Analysis (Del 8.2.1)	Report, meeting discussion between the expert groups and the modelling group.	Assumption: that the exposure models will be developed and finalised and that the team will collaborate to bring together data, expertise and the software to perform exposure assessments. Risks: Delays in delivering the exposure final assessment model, difficulty in end users running the model with their data. Contingency: The modelling group will project manage the delivery of the software on time and will organise additional workshops and training to use the tool for users.

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Logical Framework WP 9

Work-package objective	Tasks	Effort* (PM)	Expenses**	Specific results produced/ Deliverables	Sources of verification	Assumptions/Risks
9.1. To provide a database on the likely technological use of selected food additives in targeted foods	**9.1.1** Produce a list of target additives and define the relevant food categories for these additives **9.1.2** Will also identify experts in the technology of particular foods who can advise on technological use of the targeted food additives in each food group.	CIAA =6.8	*CIAA = €40k*	List of target additives Experts identified, and information on technological use of target additives gathered	Report on list of target additives and on technological use of targeted food additives	Assumption: relevant experts in technological use of food additives can be identified and will offer advice to the project Risk: Commission activities as concerns the revision of food categories could undermine the project data collection as initially foreseen Contingency: seek consistency with the Commission activities and agree on the food categories between DG SANCO and the project partners involved
9.2. To populate database with additive concentration ranges	**9.2.1** For each additive, data will be collected on the likely range of concentration of each additive	CIAA = 5.6	*CIAA = €32.9k*	Concentrations of target additives per food group compiled and database populated	Report from output of database on additive concentrations	Assumption: can gather data on target additive concentration per particular food group Risk: despite commitment of CIAA members to deliver ranges of data no contributions will be received Contingency: CIAA via its relevant internal decision making structures, namely the expert groups, FCPC and if necessary the CIAA board to request contributions.
	9.2.2 A list will also be prepared related to typical composition of the target food (upper, middle or	CIAA = 5.6	*CIAA = €32.9k*	List of typical additive compositions of target foods and database populated (Del 9.1)	Report on additive compositions of target foods	As above

	lower end of technological use).					

*Total Person Months (PM) allocated to task, **Estimated costs for salaries. Amounts in kEuro, 1 million Euro ~ 1000 kEuro

Logical Framework for WP10

Work-package objective	Tasks 3 TASKS IN TA	Effort* (PM)	Expenses**	Specific results produced Deliverables/ Contractual obligations	Sources of verification	Assumptions/Risks
10.1. Creation of project website and dissemination of project meetings	**10.1** To establish and maintain a communications programme	UCD=10 CEPE = 1 Tot: 11	*UCD = €51.5k* CEPE^	The material for the project website and a time plan for meetings with interested parties (Del 10.1 &10.2)	An active publicly available website. Reports of meetings where the dissemination programme of FACET has been implemented	Assumption: that the website is opened with a minimum of technical problems; that the meeting schedule is developed and stakeholders are willing to attend meetings; and that partners contribute to the communications plan. Risk: that the website is delayed because of technical problems, Contingency: the coordinator should seek assistance from within the consortium. If stakeholders are not interested to attend the first meetings then the meeting schedule will be carefully reviewed and changes will be implemented.
10.2. Dissemination of development results	**10.2** Dissemination of development results	JRC: 7 CREMe: 2 CEPE = 2	*JRC = €36.4k* *CREMe =8.1k* CEPE^	Training Manual for Software and dissemination (Del 10.3 & 10.4)	Minutes of meetings, dissemination materials distributed and tracked.	Assumption: the software groups will completion of the software training manual and the organisation of dissemination events by the partners. Risks: non completion of

		Tot: 11				manual and difficulty in organisation of dissemination events. Contingency: Increased project management of the delivery of the manual and the group will seek assistance from the coordinator if difficulties in organising dissemination events arise.

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