EU Project QLK1-CT2002-2390

FOOD MIGROSURE

Modelling migration from plastics into foodstuffs as a novel and cost efficient tool for estimation of consumer exposure from food contact materials

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First of all:

Thank you all for your interest in our project and for coming!

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Contents

- **Why did we get into this project?**
  [or:
  Why was the project unavoidable?]

- **Intention & structure of the project**

Why the project?

Migration tests should be

simple and reproducible

and have therefore been carried out so far using in the first place

food simulants
and not foodstuffs.

Why the project?

On the other hand:

EU legislation foresees that for compliance

the concentration (migration) in food

is the crucial one compared to the food simulant test.

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Why the project?

And:

Exposure estimation or assessment should (must) be based on

the concentration (migration) in food

and not on migration values in food simulants.

Why the project?

Consequently,

a correlation is needed between
food simulants and foods

which is the intention of
EU Directive 85/572/EEC.

However, problems were getting more and more evident over the years .....

Why the project?

... for instance with these examples: (where migration is given as relative values: food / olive oil)

(Source: EU Report 19376 EN)

Food item	RF	Relative migration default	Relative migration measured
Chocolate spread	X/3	0.33	up to 1
Chocolate	X/5	0.2	up to 1
Salami	X/4	0.25	up to 0.88
Cocoa powder	X/5*	0.2	up to 0.85
Mayonnaise (low fat)	X/3	0.33	up to 0.83
Mayonnaise	X/3	0.33	up to 0.80
Peanuts	X/5*	0.2	up to 0.52
Butter	X/2	0.5	up to 0.57
Cheese (low fat)	X/3*	0.33	up to 0.19
Whole milk	(A)	n.a.	up to 0.27
Irish cream liqueur	(C)	n.a.	up to 0.45
Flour	(NT)	0	up to 0.42
Buiscuit (rich tea)	(NT)	0	up to 0.58
Bread	(NT)	0	up to 0.08

Why the project?

More recent examples from the ‚ITX crisis' [photo initiator in printing inks transferred to food via set-off] revealed again weaknesses of the 85/572/EC system

Why the project?

ITX and EHDAB levels in "cloudy" drinks (fruit juices/nectars)

Product	Pack size(ml)	ITX (µg/l)	EHDAB (µg/l)
Apple/acerola juice	200	45	16
Apricot nectar	200	63	33
Orange juice	200	136	46
Orange juice	200	201	88
Multivitamin drink	200	30	17
Multivitamin juice	200	249	125
Peach nectar	200	95	35
Pear juice	200	70	24
Pineapple juice	200	32	10

... altogether 45 products measured with found concentrations for
- ITX between 20 ppb and 250 ppb
- EHDAB between 10 ppb and 125 ppb

(Source: EFSA opinion on ITX and EHDAB in FCM, dated 7 December 2005)

Why the project?

ITX and EHDAB levels in "clear" drinks (fruit juices/nectars)

Product	Pack size (ml)	Juice content (%)	ITX (µg/l)	EHDAB (µg/l)
Apple juice	1000	100	< 5	< 5
Apple juice	1000	100	< 5	< 5
Apple pear drink	1000	6	< 5	< 5
Cherry drink	1000	35	< 5	< 5
Cranberry & Raspberry	1000	21	< 5	< 5
Cranberry drink	1000	25	< 5	< 5
Elder flower drink	1000	22	< 5	< 5
Fruit drink	1000	20	< 5	< 5
Juice/alcohol drink	1000	15% alcohol	< 5	< 5

(Source: EFSA opinion on ITX and EHDAB in FCM, dated 7 December 2005)

... altogether 17 products measured and in all cases found concentrations were not detectable, i.e < 5 ppb

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Why the project?

ITX and EHDAB levels in milk and soy beverages

Product	Fat content (%)	ITX (µg/l)	EHDAB (µg/l)
UHT milk	3.8	142	71
UHT milk	1.5	177	92
UHT milk	0.1	54	27
Soy milk	1.5	219	134
Soy milk vanilla	1.5	170	90
Soy milk & juice	0.6	137	71
Chocolate milk	2.9	295	148

(Source: EFSA opinion on ITX and EHDAB in FCM, dated 7 December 2005)

It should be noted that water and 10% ethanol would give 'not detectables' (< 5ppb)

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Why the project?

Further advantageous circumstances were that...

... enormous progress has been made over the last decade in migration modelling, in particular for mono-plastics in contact with food simulants, but also for multi-layer plastics.

... essential developments have been made in the area of certified or certifiable reference plastics films in relation to migration relevant specifications.

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www.foodmigrosure.com

Modelling Migration from Plastics into Foodstuffs as a Novel and Cost Efficient Tool for Estimation of Consumer Exposure from Food Contact Materials

Total project costs: 2.35 Mio €

Process Engineering and Packaging IVV
Giggenhauser Str. 35

Duration: 43 months
End of project: 30th September 2007

EU contribution: 1.19 Mio €

Scientific Officer: Mrs. Dyanne Bennink, European Commission DG Research
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Project partners

No. LOGO	Partner
(01) FhG IVV	Fraunhofer Institute for Process Engineering and Packaging, Freising, DE
(02) DEFRA-CSL	Central Science Laboratory, Dept. Food Environment & Rural Affairs, York, GB
(03) [illegible]	[illegible]
(04) FIRA	Fira International, Leatherhead, GB
(05) EC-JRC-IHCP	EC Joint Research Centre, Inst. Health and Consumer Protection, IT
(06) [illegible]	University [illegible]
(07) TUV IFCFT	Vienna University of Technology, AT
(08) NESTLÉ RC	Nestlé Research Centre, Lausanne, CH
(09) CEFIC-FCA	European Chemical Industry Council, Food Contact Additives Panel, Brussels, BE

9 Partners from 7 European countries including 1 European Association

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The idea

The basic equation to calculate FCM related exposure:

$$Exposure = \frac{\sum C_i \cdot P_i \cdot M_i}{\sum C_n}$$

via migration modelling

where:

- C_i = **consumption rate of a particular food *i***
- P_i = **relative packaging usage of a given FCM for a particular food *i***
- M_i = **migration rate from a given FCM into a particular food *i***
- n = **number of foodstuffs considered for the exposure estimation**

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Main Objective

.... was to develop an into-food migration model as a novel and economic tool that may be applicable in two different ways:

(1) As a stand alone tool to estimate exposure related migration within the conventional frame conditions of the EU food regulatory evaluation system thus applying a worst case exposure scenario, i.e.:

$$Exposure = \sum M_i$$

(2) In conjunction with statistical data obtained from food consumption and plastics packaging surveys to estimate realistic or worse-case exposure for any situation of interest, i.e.:

$$Exposure = \frac{\sum C_i \cdot P_i \cdot M_i}{\sum C_n}$$

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Project structure

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Ian Cooper

Ingrid Steiner

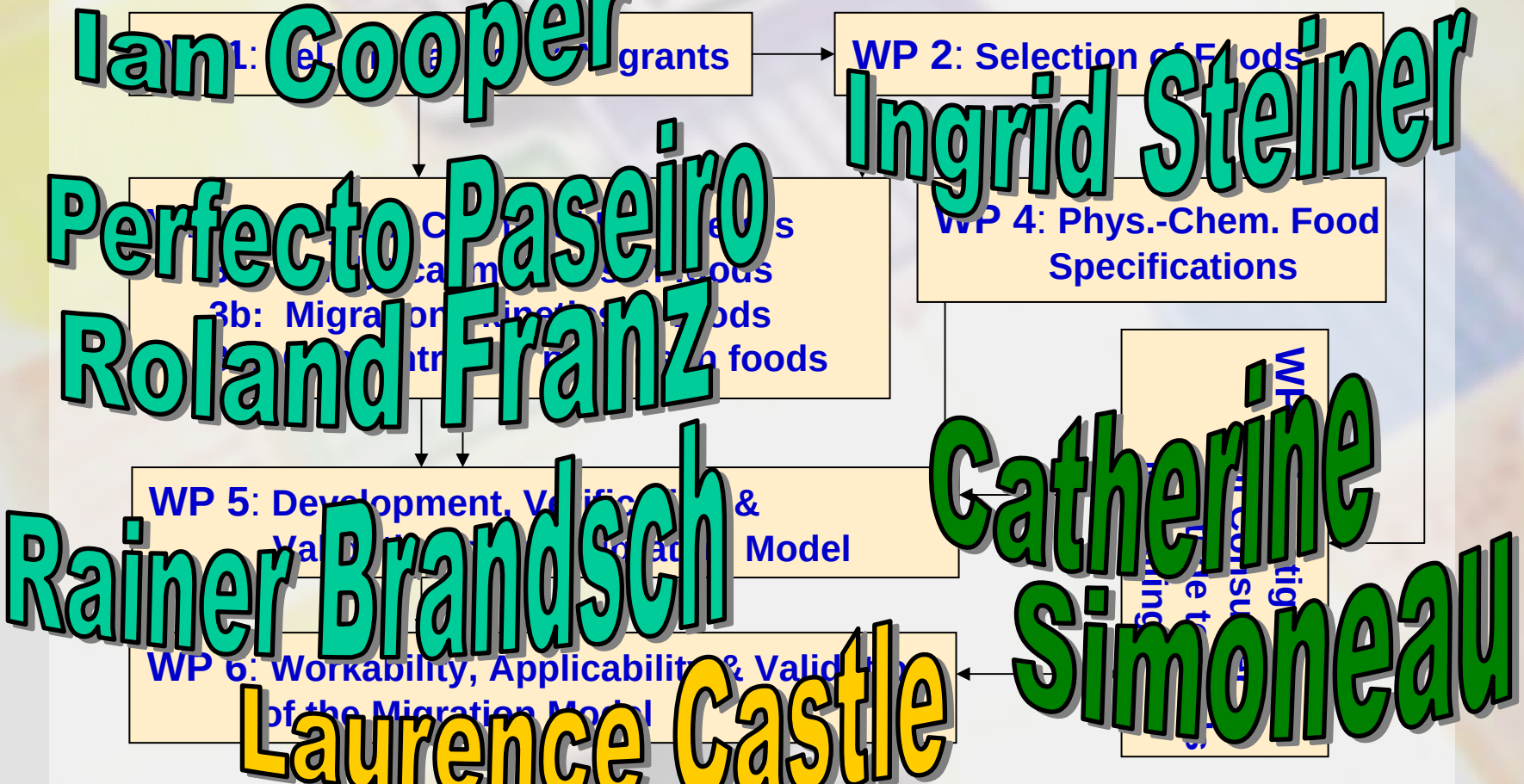
Perfecto Paseiro

Roland Franz

Rainer Brandsch

Catherine Simoneau

Laurence Castle



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Expected Benefits

.... for EU Commission and EFSA

In general:

Supporting present and future EU legislation for FCM

In particular:

- **Scientific/technical basis for actualisation of Directive 85/572/EEC issues**
- **Bringing more light into the dark related to meet specific restrictions (SMLs) on the level of foodstuffs**
- **Supporting and plausibilisation of exposure estimations in context with petitions and setting specific restrictions**

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Expected Benefits

.... for Industry

Packaging industry:

- Early (in the packaging development process) and food type specific compliance evaluation
- Cost efficient compliance ensurance

Food industry:

- Improving or even establishing independent house-internal quality assurance tools and this in a better product specific way
- More knowledge about diffusion and partitioning processes or organic compounds in foods

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Expected Benefits

.... for the Consumer including 'consumer protectors'

- Better and more effective surveillance of FCM
- (Further) familiarisation with the idea of 'Migration Modelling' and increasing acceptance of calculated migration values
- (Somewhat) cheaper packed foodstuffs?

And with the possible effect of ...

decreasing the FCM related conflict potential and generating more confidence in FCM safety?

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