資料３

European Food Safety Authority

Evaluation of substances for positive lists for Food Contact Materials

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Head of CEF Unit
Food Contact Materials, Enzymes, Flavourings & Processing Aids

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European Food Safety Authority

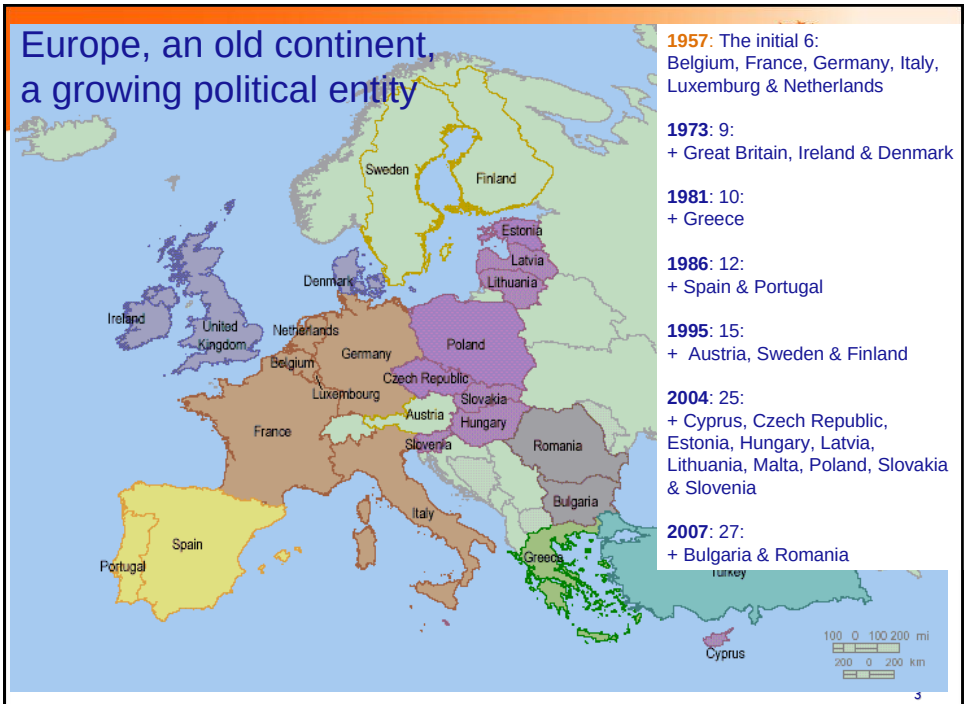
About EFSA and evaluations for FCM

Evaluations for positive lists

Risk assessment in case of crises

2

Europe, an old continent, a growing political entity



1957: The initial 6:
Belgium, France, Germany, Italy, Luxemburg & Netherlands

1973: 9:
+ Great Britain, Ireland & Denmark

1981: 10:
+ Greece

1986: 12:
+ Spain & Portugal

1995: 15:
+ Austria, Sweden & Finland

2004: 25:
+ Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia & Slovenia

2007: 27:
+ Bulgaria & Romania

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Background of creation of EFSA (2003)

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- **Succession of food scares**
  (e.g. Bovine Spongiform Encephalopathy, dioxins)
- **Loss of consumer confidence in safety of food chain**
- **Damaged trust in public authorities**
- **Need to re-cast EU food safety system and policy**

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Regulation EC 178/2002: "Food law", the legal background

- General principles for food safety requirements
- Setting up the European Food Safety Authority
- Setting up a procedure for managing crises
- Provides the respective responsibilities risk assessment / risk management.

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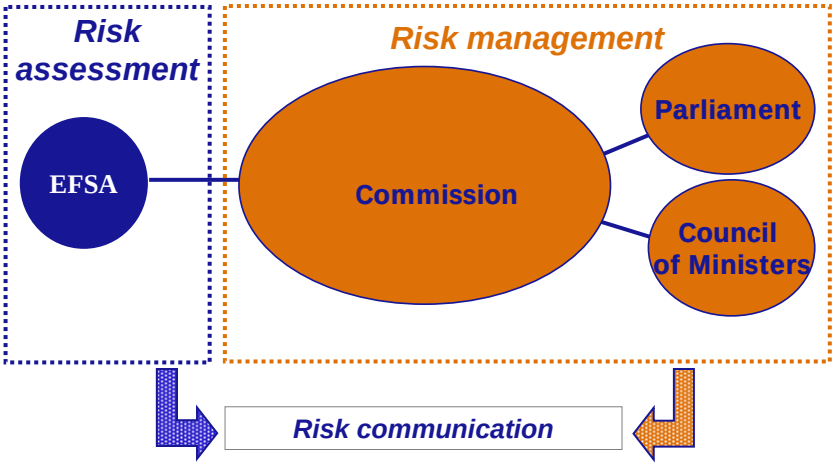
EU Food Safety Structure



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What EFSA does: the mandate

- **Provide scientific advice** and support for Community legislation/policies in all fields with direct/indirect impact on food and feed safety
- **Provide independent information** on all matters within these fields
- **Risk communication**

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About risk communication

Risk Communication: deliver a simple and clear message

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Commission does not always follow EFSA's advice

Example: EFSA has evaluated several biocides for FCM and considered uses as acceptable from point of view of food safety.

Commission (risk manager) has not authorised them (EC 975/2009), because of other considerations (e.g. broad use of biocides may raise concerns for antimicrobial resistance).

Such considerations were not in EFSA's mandate.

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Daily Mail

THURSDAY, OCTOBER 14, 2003 NEWSPAPER OF THE YEAR 40p

It's not too late to pick up this week's children's classic with your Mail FOR JUST £2.60

Robert Louis Stevenson

Treasure Island

JARS OF BABY FOOD IN CANCER ALERT

BABY food firms have been warned to change the seals on their jars amid fears of contamination by a cancer-causing toxin.

Lady in blue

Camilla Parker Bowles arriving at the Fashion Rocks charity extravaganza in London last night

SEE PAGES 8 & 9

...tion

Consumers have a strong concern for safe food packaging

⇒ interest of NGOs & media

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The 4 pillars of EFSA

Management Board + Advisory Forum + EFSA Staff + Scientific Committee and Panels = efsa European Food Safety Authority

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Commission Parliament Members States Self mandate

* Commission
* Parliament
* Member States
& EFSA (self-mandate)

may put questions to EFSA

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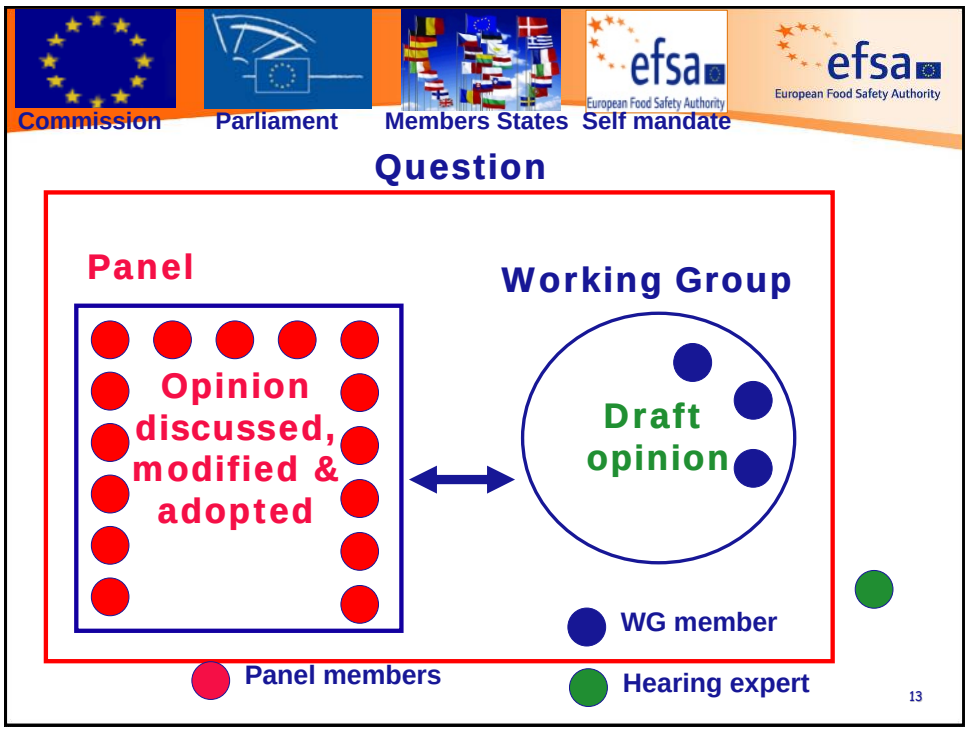
Commission
Parliament
Members States
Self mandate
efsa
European Food Safety Authority
Question
Panel
Working Group
Opinion discussed, modified & adopted
Draft opinion
WG member
Panel members
Hearing expert
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Commission
Parliament
Members States
Self mandate
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Panel may send back a draft opinion to the WG for clarification & improvement
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Commission Parliament Members States Self mandate

EFSA does not decide on priorities: they are set in Terms of Reference. For positive list, it is even set in Regulation: it is always the same: 6 months!

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EFSA selects the WG & Panel Members

Is he/she the one who shows the way?

-Proven scientific excellence
-Experience in risk assessment
-Absence of conflict of interest

⇒ **Appointment for 3 years in Panel of 21 members**

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EFSA selects the WG & Panel Members

Experts & rapporteurs are external
(= not paid by EFSA).
This guarantees independency of opinions.

A decision of a Panel cannot be contradicted by EFSA.

EFSA scientific secretariat heavily contributes to consistency of opinions, mainly at WG level.

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EFSA selects the WG & Panel Members

Experts are highly committed:
At each meeting (WG or Panel) 10-20 daft opinions are discussed,
each with 20-60 pages,
received 1-3 weeks in advance.

And the experts always know all documents & follow the discussions….!

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EFSA selects the WG & Panel Members

Experts are highly committed:

- No financial interest, only indemnities
- Discussions at high level
- All relevant areas of science are represented in meetings
- Discussions are intellectually challenging
- EFSA acknowledges its experts
- Experts are proud of being selected by EFSA

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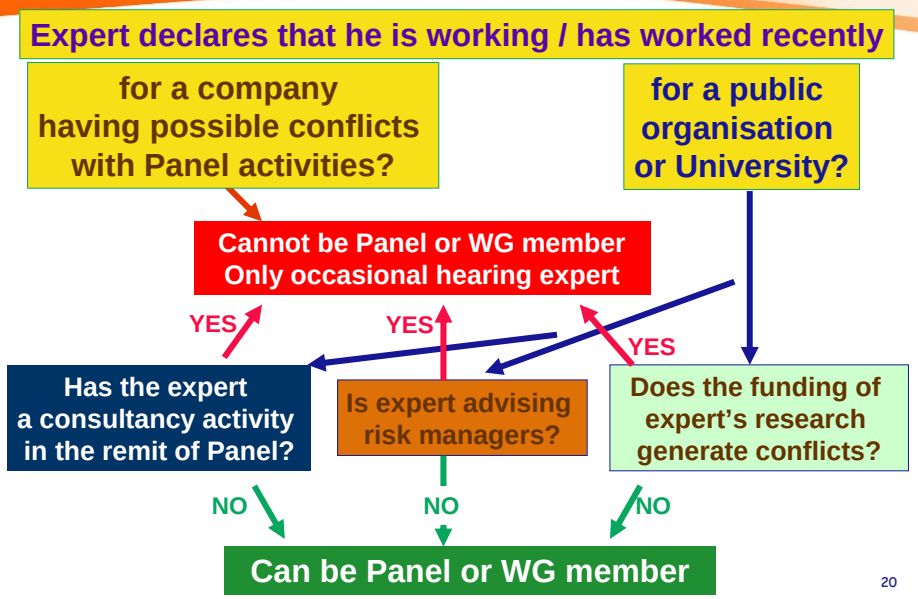
Management of conflicts of interest



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About EFSA and evaluations for FCM

Evaluations for positive lists

Risk assessment in case of crises

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Is my food safe?

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Plastics Packaging materials are regulated with positive list

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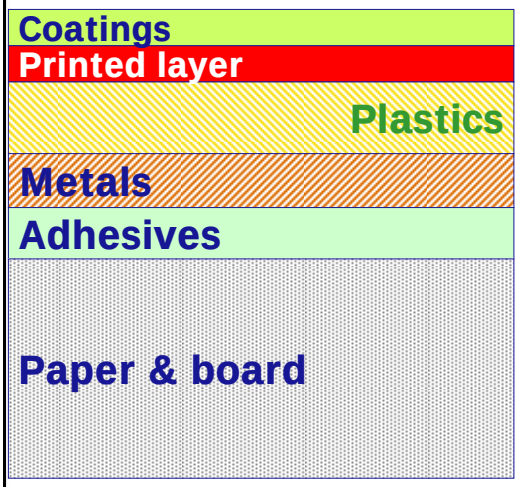
Cross section of a typical packaging material



1935/2004

1935/2004

2002/72-Positive list (monomers, additives)

1935/2004

1935/2004
Only general requirement: "should not endanger human health"
No positive list.

Silicones, rubber, wood chips ….

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Principle of positive lists

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A positive list is a list of substances which have been evaluated and which may be used to make FCM materials.
Only substances from the list can be used.

Historically there were 2 list as annexes, both for monomers & additives
-**List A: Substances evaluated** (the real future positive list)
-**List B: Substances not yet evaluated and which can be used provisionally** if **a valid application has been submitted by a given deadline**

Only list A is the actual positive list
The list is positive when list B disappears.

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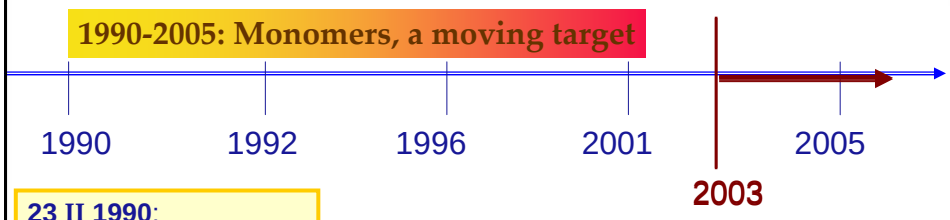
Historical background: Postponements of deadline for applicants by Commission (Risk Manager)



23 II 1990: two lists of authorised monomers:
- list A (substances evaluated) finalised by **1 I 1993**
- list B (not yet evaluated) finalised by **1 I 1992**

Positive list postponed four times!

1 I 2005: the list becomes a positive list. No list B anymore!

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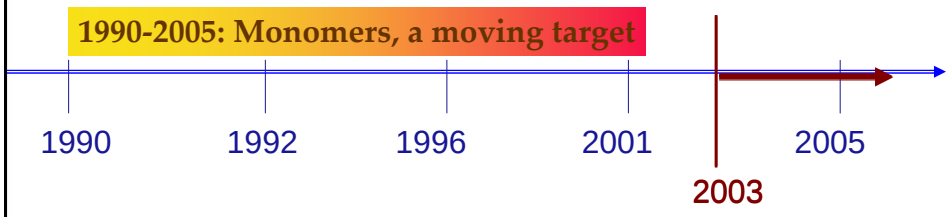
Historical background: Postponements of deadline for applicants by Commission (Risk Manager)



The reason of postponement from 1992 to 2005 was the time necessary
-to obtain the needed toxicological data for some substances, important from the economic point of view and for the plastics technology
-for extinction of list B (older regulations in MS)

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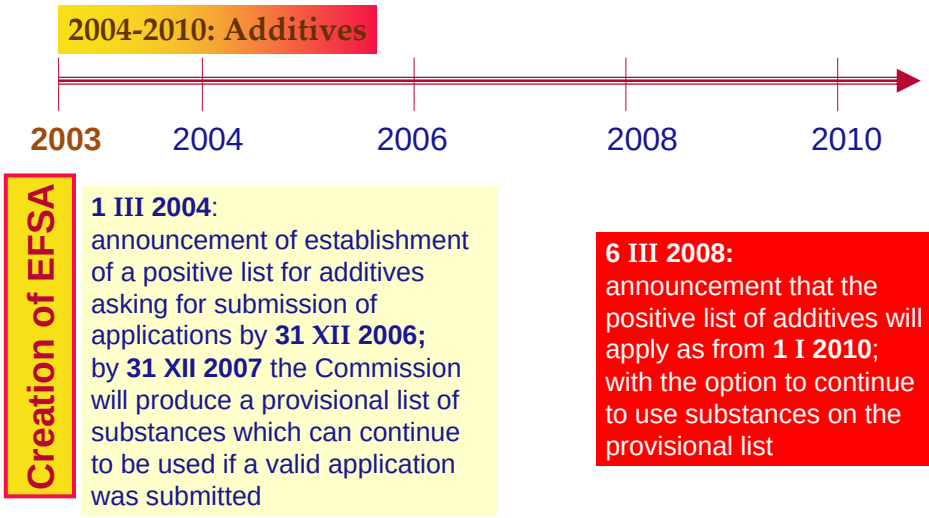
Historical background: additives



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Responsibilities of business operators

- **Any food in which a specific migration limit (SML) is exceeded is illegal, whatever the size and amount on the market (independently of actual dietary exposure): e.g. mineral water as well as anchovies**

  High consumption (2 l/day)

  low daily consumption

- **Every business operator has to comply with the regulation and the migration limits, whatever the amounts of packages or packaged food he places on the market**

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Responsibilities of business operators

- Raw Materials Manufacturer
- Plastics converter
- Packer-filler - Food industry
- Retailer
- Consumer

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Responsibilities of business operators

European Food Safety Authority

- Raw Materials Manufacturer
- Plastics converter
- Packer-filler - Food industry
- Retailer
- Consumer

Knowledge on FCM

Responsibility for FCM defects

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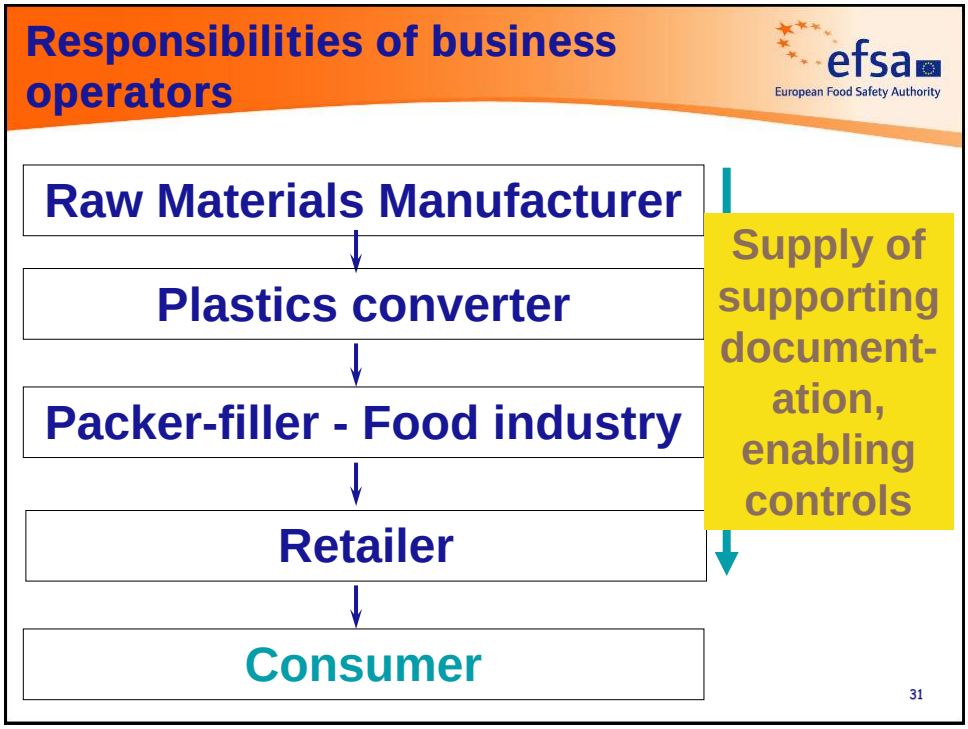
Responsibilities of business operators
efsa
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Raw Materials Manufacturer
Plastics converter
Packer-filler - Food industry
Retailer
Consumer
Supply of supporting document-ation, enabling controls
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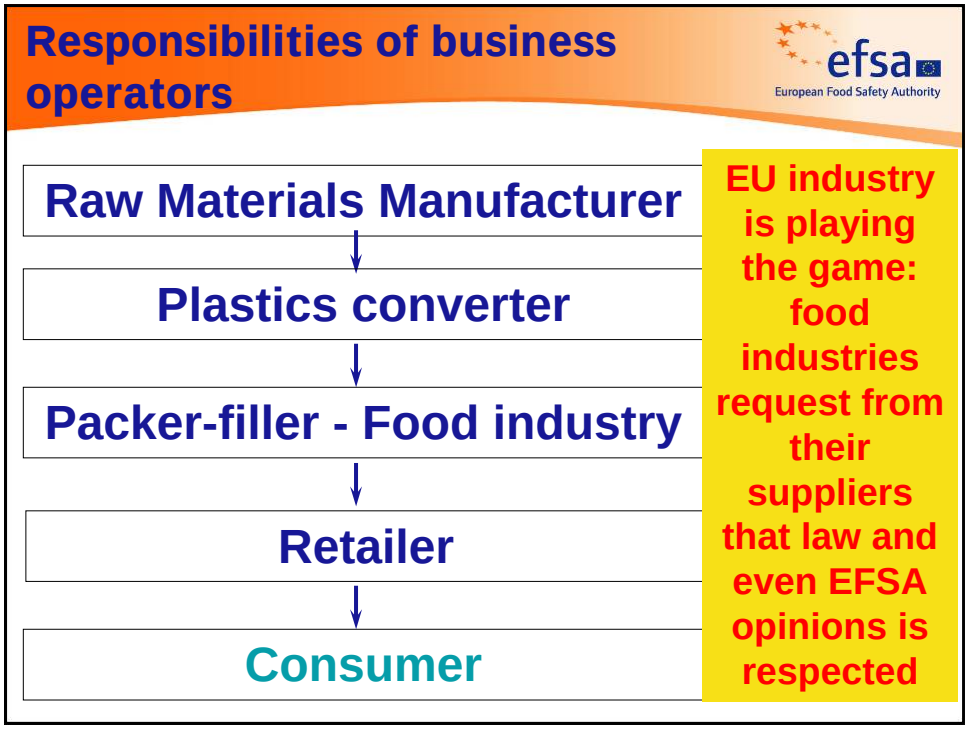
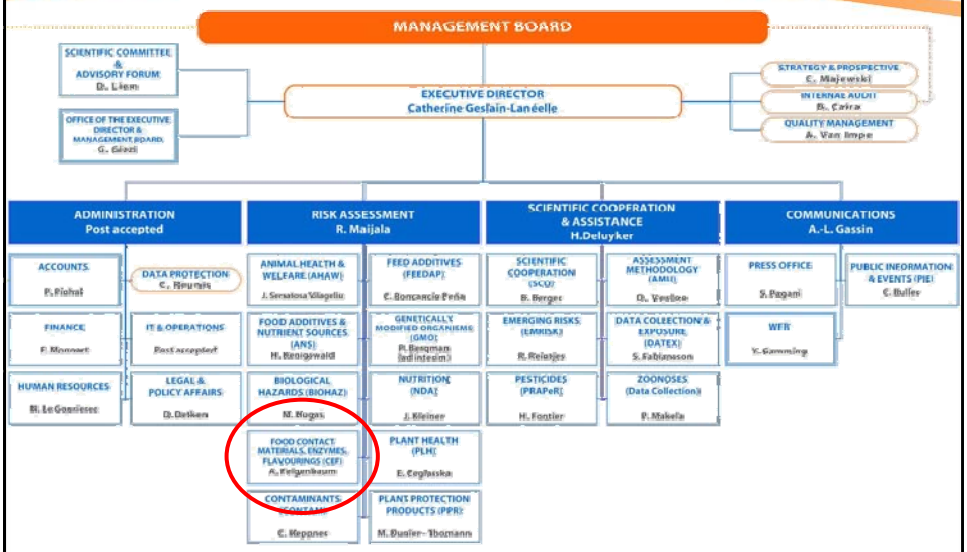

Responsibilities of business operators
efsa
European Food Safety Authority
Raw Materials Manufacturer
Plastics converter
Packer-filler - Food industry
Retailer
Consumer
EU industry is playing the game: food industries request from their suppliers that law and even EFSA opinions is respected

EFSA organigramme



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EFSA organigramme

Food Contact Materials team in CEF scientific secretariat

-**Dimitrios Spyropoulos**, deputy Head of Unit

-Eric Barthelemy, junior scientific officer

+ part time contributions of

- Eva Maria Ferrari, administrative assistant
- Anna Castoldi, senior toxicologist
- Alina Lupu, junior scientific officer
- Ilse Koenig & Marco Lannutti, web site, finance

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Two types of evaluations for FCM

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APPLICATIONS
for positive lists-substances not yet on the market

Full risk assessment for substances already on the market & CRISES:
ITX, benzophenone, 4-MBP, bisphenol A

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Applications for positive lists: the launching

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Company (applicant) prepares an application
-for a new substance for plastics
-to request new conditions of use for an "old " substance

↓

Company follows EFSA guidelines
-to identify the data needed for the specific case
-to set up the dossier

↓

Company sends the application to a Member State

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Applications for positive lists: the workflow

First check of application: Member State checks the compliance of application with Regulation (intended use is plastics) or sets another priority & sends it to EFSA with a mandate (background + terms of reference)

↓

Second check: EFSA receives the application
CEF Unit checks the completeness of the application and appoints rapporteurs, in agreement with Chair

↓

Third check: Rapporteurs check the scientific validity of application: have all data been provided?
If not, has a scientific justification been provided?

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Applications for positive lists: the workflow

Official acceptance:
Clock starts: 6 months!

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Applications for positive lists: the workflow

During these 6 months, EFSA Secretariat has a very important administrative and scientific work:
-organisation of meetings, travels, Declarations of interest…
-coordination between rapporteurs, scientific documentation, consistency of final report, communication…

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Applications for positive lists: the workflow

Steps after acceptance by EFSA of dossier for evaluation

1. **Preparation of draft report**
2. **Discussion of draft report in CEF FCM Working group** (5-6 meetings per year, 2.5 days each)
3. **Discussion of draft report in CEF Panel => opinion** (5-6 meetings per year, 2.5 days each)
4. **Publication of opinion on EFSA home page** (15 working days after adoption)

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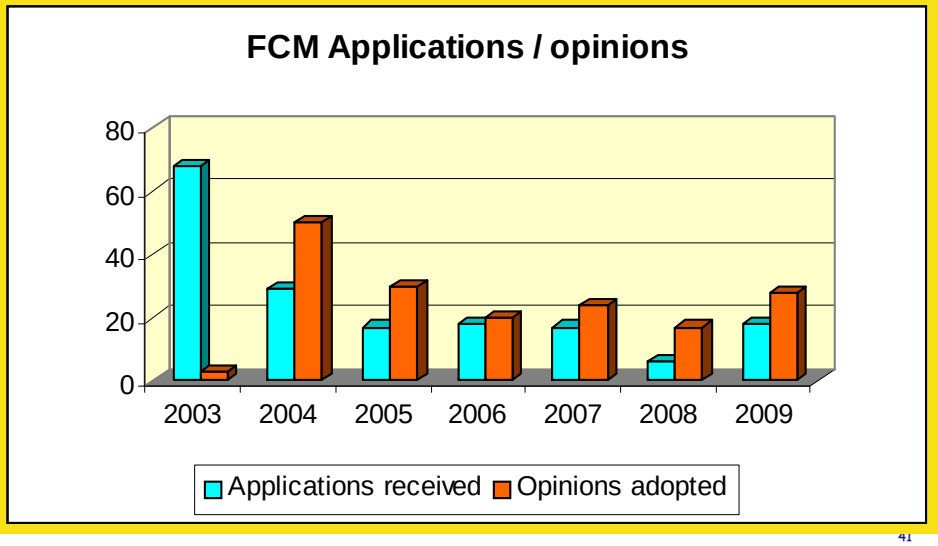
Applications for positive lists: the workflow



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Applications for positive lists: the principles

APPLICATIONS
for positive lists- substances not yet on the market:

- **Dietary exposure is estimated based on conventional worst case scenario**
- **Set of toxicity data requested is based on migration values in food simulants**

Applicants MUST provide the data according to EFSA guidelines.

If at validity check, it is seen that data are missing, the application is not accepted.

If during evaluations, it appears that data submitted are not adequate, additional data are needed and the clock is stopped.

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Applications for positive lists: the principles

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Toxicology

⇓

TDI

Tolerable Daily Intake

⇓⇑

SML

Specific Migration Limit or Migration Restriction

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Applications for positive lists: the principles

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❶ A (high/standard) consumer weights **60 kg**

❷ **He/she consumes every day of his/her life 1 kg of food packaged with the FCM material containing the FCM substance**

❸ **6 dm² plastic package 1 kg food**

⇒ **SML (mg/6 dm²) = TDI (mg/kg body weight) / 60**

Specific Migration Limit
Migration is tested in food simulants
(aqueous, alcohol, acid, fatty)

Tolerable daily intake
or restriction
(from toxicity data)

Consumer weight (60 kg)

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Applications for positive lists: the threshold approach

	< 0.05 mg/kg	< 5 mg/kg	5-60 mg/kg food
3 mutagenicity tests	+	+	+
90-day study	-	+ (1)	+(2)
accumulation	-	+	-
ADME	-	-	+
reproduction study	-	-	+
developmental studies	-	-	+
long term study	-	-	+

No migration should exceed 60 mg/kg food

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Applications for positive lists: expressing restrictions

If only 3 genotoxicity tests are provided and if they are negative, can the conclusion of the evaluation be "migration acceptable till 0.05 mg/kg food"?

Answer: NO

Migration data are always requested
-They correspond to intended use
-They represent worst case situations (time, temperature)
-Applicants must demonstrate that they are able to manufacture materials complying with the likely migration restriction

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Applications for positive lists: expressing restrictions

3-Methyl-1,5-pentanediol, a co-monomer for polyurethane, was shown by applicant to be non genotoxic.
Conclusions of the evaluation were as follows:
-**SML = 0.05 mg/kg food**
-**Only to be used in materials in contact with food at a surface to mass ratio up to 0.5 dm²/kg food** (e.g. sealing gaskets)

With such a restriction, there is no safety concern about possible migration of cyclic polyurethane oligomers (EFSA October 2009).

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About EFSA and evaluations for FCM

Evaluations for positive lists

Risk assessment in case of crises

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Substances already on the market, no application: crises!

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APPLICATIONS
for positive lists-substances not yet on the market:

- Dietary exposure is estimated based on conventional worst case scenario
- Set of toxicity data requested is based on migration values in food simulants

Full risk assessment for substances already on the market & crises:
ITX, benzophenone, 4-MBP, bisphenol A

- Dietary exposure is estimated based on surveys in foodstuffs
- Extensive use of all data available: scientific literature & industry data and cross-reading

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Substances already on the market, no application: crises!

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Crises are for special requests on substances - not covered by positive lists (not used for plastics): inks, coatings, adhesives, paper & board -with emotional content (Bisphenol A, BPA)

In principle the deadline can be negotiated (contrary to the 6-months deadlines for positive lists).

Full risk assessment for substances already on the market & crises:
ITX, benzophenone, 4-MBP, bisphenol A

- Dietary exposure is estimated based on surveys in foodstuffs
- Extensive use of all data available: scientific literature & industry data and cross-reading

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Requests for substances already on market usually from non plastics FCM

Cross section of a typical packaging material

Coatings	1935/2004
Printed layer	1935/2004
Plastics	2002/72-Positive list (monomers, additives)
Metals	
Adhesives	1935/2004
Paper & board	1935/2004 Only general requirement: "should not endanger human health" No positive list.

Silicones, rubber, wood chips ….

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Substances already on the market, no application: crises!

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Substances already on the market, no application: crises!

Questions arrive from Commission (risk manager) or Member State.
The Rapid Alert System for Food and Feed (RASFF) between Member States if activated.

When industry has little information available, there is a crisis: loss of consumer's confidence, economic losses for food companies…
and high pressure on EFSA, which has to tell what is safe and what is not safe.

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Substances already on the market, no application: crises!

EFSA receives a question for urgent scientific advice about the risk when food is contaminated by

- a non evaluated FCM substance
- an evaluated FCM substance migrating > SML

These situations jeopardize the usual workflow.

In such cases, evaluations are usually based on:
-Survey studies of dietary exposure to the substance itself or to an equivalent substance
-Read across from similar substances for toxicity assessment, when not enough data available
-Any literature data available, which is evaluated.

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The 4-methylbenzophenone case (4-MBP)

- On 2 February 2009, the German authorities have notified through the Rapid Alert System for Food and Feed the migration of 4-MBP from packaging into some breakfast cereals, in a concentration of 0.8 mg 4-MBP/kg food. The Belgian Authorities later reported concentrations up to 5.4 mg/kg.
- Commission has asked EFSA about **urgent scientific advice**
- It was not possible to negotiate the deadline, due to high pressure (should the food be withdrawn from stores ...?)

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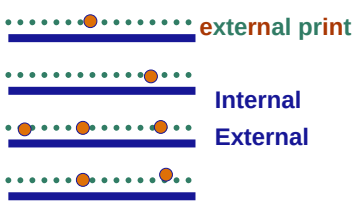
The 4-methylbenzophenone case (4-MBP)

4-MBP, a constituent of prints, is transferred by a set-off mechanism from the outside, printed surface to the inside surface, which comes in contact with food (set-off mechanism)



Ink constituents contaminate the inner surface of packaging films

When food is packaged, it becomes contaminated with the ink constituents

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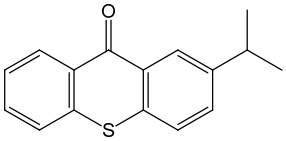
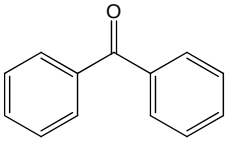
The 4-methylbenzophenone case (4-MBP)

ITX (2005)

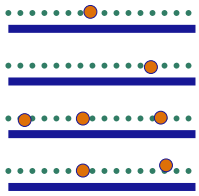


2-isopropylthioxanthone

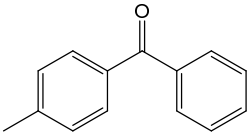
BP (2006)
benzophenone



benzophenone



4-MBP (2009)



4-methylbenzophenone

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The 4-methylbenzophenone case (4-MBP)

No data available on 4-MBP. More data on BP

⇒ **OPINION IS BASED ON READ-ACROSS FROM BP:**

❶ 4-MBP and BP have similar chemical structure. However the slight differences do not allow that the TDI of BP is applied to 4-MBP.

❷ Read-across from BP requires an additional uncertainty factor.

An acceptable **Margin of Safety** is defined.

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Substances already on the market, no application: crises!

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Possible ways to improve both the workload and the efficiency of work could be
-pre-screening approaches for chemicals
-better communication between agencies, which are often facing the same or similar issues.

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EFSA Staff

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Thanks you for your attention

let us contribute
together to a safe food
&
safe food packaging

《講師プロフィール》

アレキサンダー・フェイゲンバウム博士

(Dr. Alexandre FEIGENBAUM)

略歴

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1988-2008　フランス国立農業研究所（ＩＮＲＡ）　研究所長

1988-2003　食品科学委員会（ＳＣＦ：ＥＦＳＡの前身）食品接触物質パネル専門委員

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2008-　　欧州食品安全機関（ＥＦＳＡ）食品接触物質パネル座長

2003-2007　フランス食品衛生安全局（ＡＦＳＳＡ）食品接触物質パネル座長