CATÓLICA PORTO
BIOTECNOLOGIA

Safety aspects related to paper use for food contact materials and packages

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COST Action
Active and intelligent fibre-based packaging - innovation and market introduction
University of Aveiro, Portugal 15th September 2015

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EUROPEAN COOPERATION
IN SCIENCE AND TECHNOLOGY

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Horizon 2020

ActInPak

Agenda

- Introduction
- Safety aspects
    - (In) direct contact
    - Composition
    - Technology
- Legislation
    - European
- Active & Intelligent

Introduction

- Risk assessment

$$Risk = Exposure \; x \; Toxicity$$

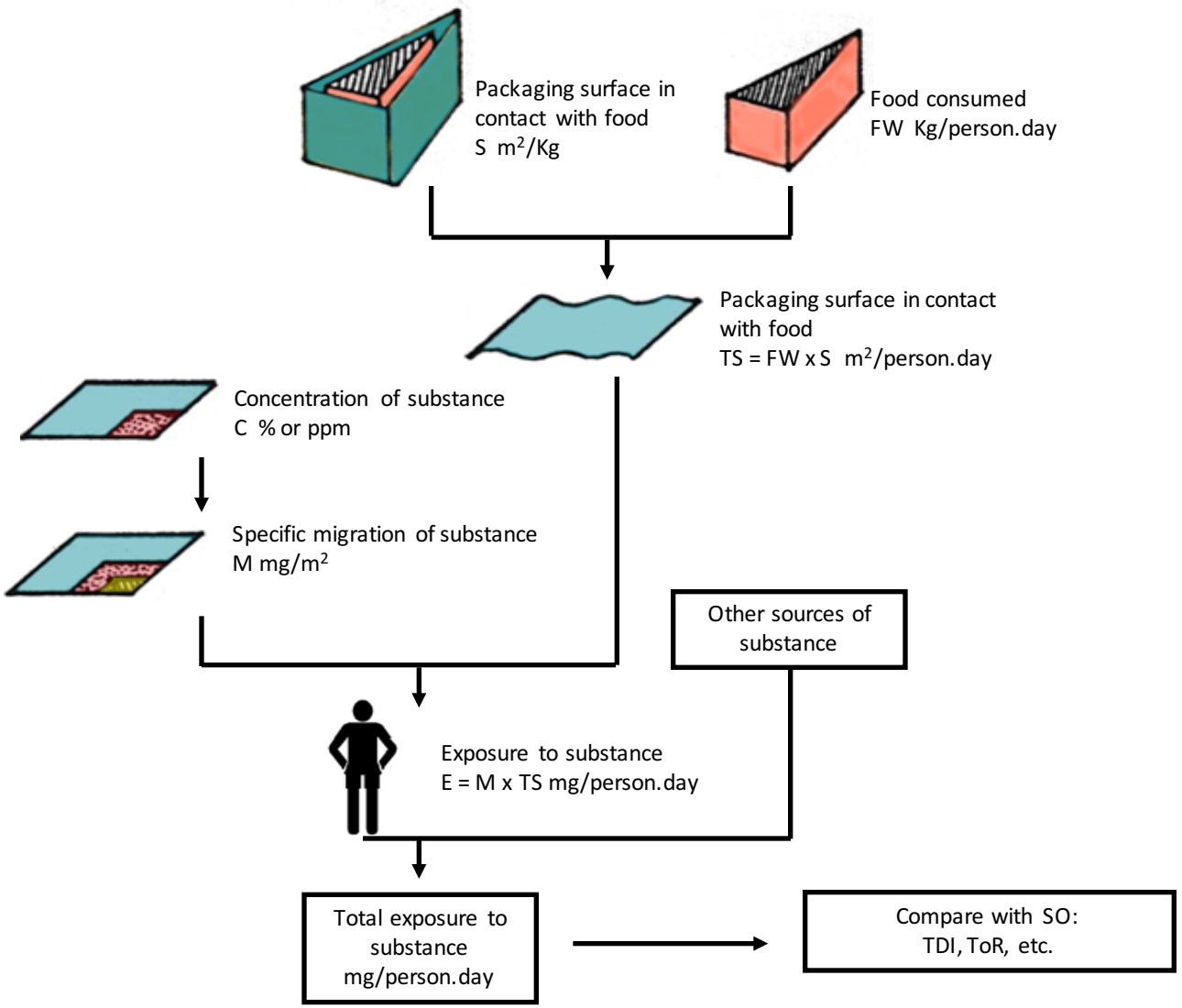
- Exposure to chemicals from PMC

$$Exposure = Migration \; x \; Consumption$$

  - Exposure is based on average worst case of packaged food usage
  - Compare Exposure with toxicological criteria ADI, TDI, etc.

Introduction

- Principle



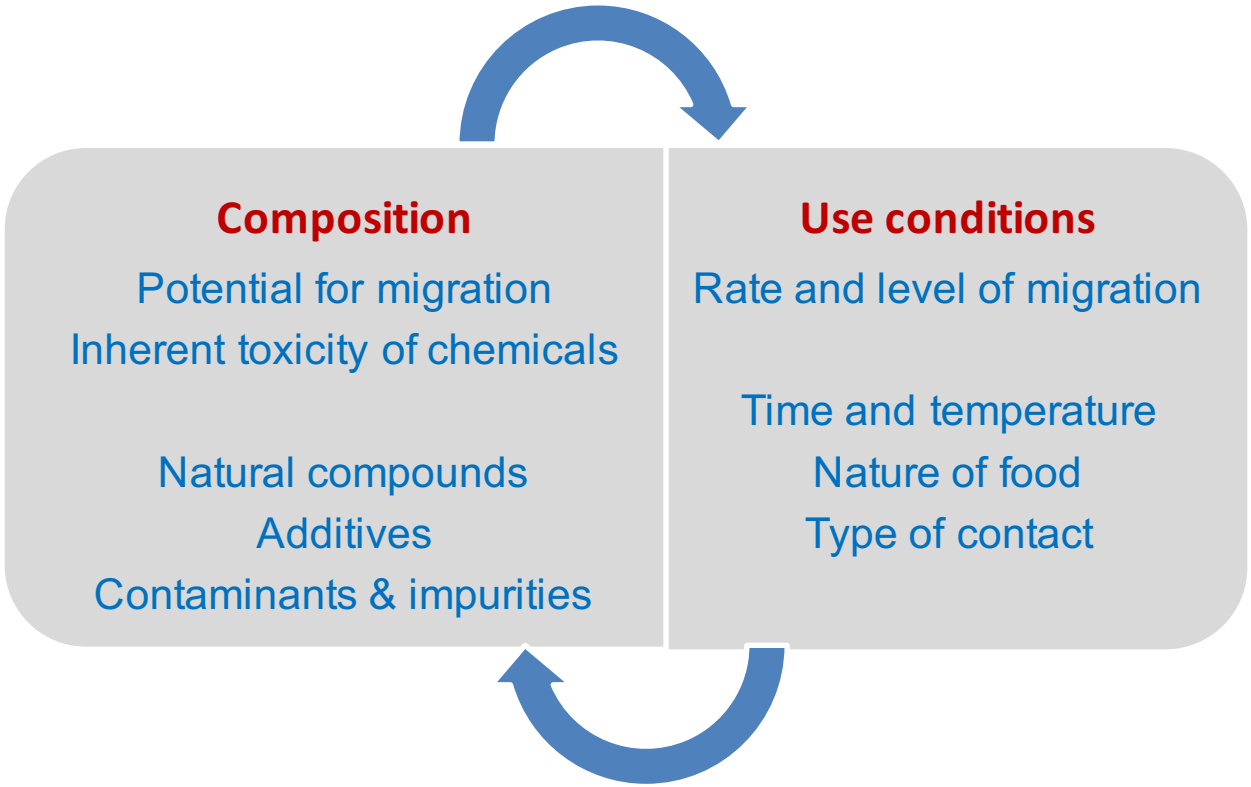
Base:

1 kg_{food}/person.day

6 dm^2/Kg_{food}

60 kg_{bw}/person

Safety


Composition
Potential for migration
Inherent toxicity of chemicals
Natural compounds
Additives
Contaminants & impurities
Use conditions
Rate and level of migration
Time and temperature
Nature of food
Type of contact

Safety

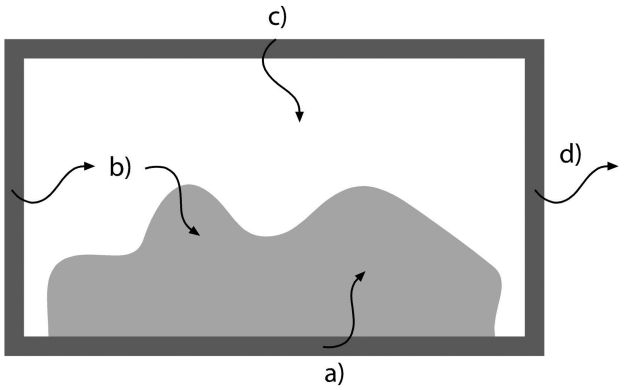
- Type of papers and board (P&B) and uses
  - Transport and distribution packaging
  - Intimate contact (tea bags, baking papers, and filters)
  - Direct contact (butter wrapping, sugar bags, and cartons for dry and frozen foods)

Safety

- Composition
  - Around 99% of **cellulose fibres**
  - **Naturally occurring** minerals (calcium carbonate) and starch
  - **Added chemicals** (less than 1% by weigh)
    - Functional additives (intended to have a technical effect in the P&B)
    - Process chemicals or processing aids to improve the efficiency of the papermaking process; are not intended to remain in P&B and are usually washed out during the papermaking process
  - **Recycled fibres**
    - Most important source of safety issues
    - NIAS – non-intentionally added substances

Safety

- Use conditions
  - Time and temperature of contact
  - Nature of food
    - Solid vr liquid
    - Chemical properties (fatty, aqueous, etc.)
  - Type of contact
    - Direct/non direct (through head-space)
    - Presence of barrier
    - Migration per set-off
      - MBZF gate

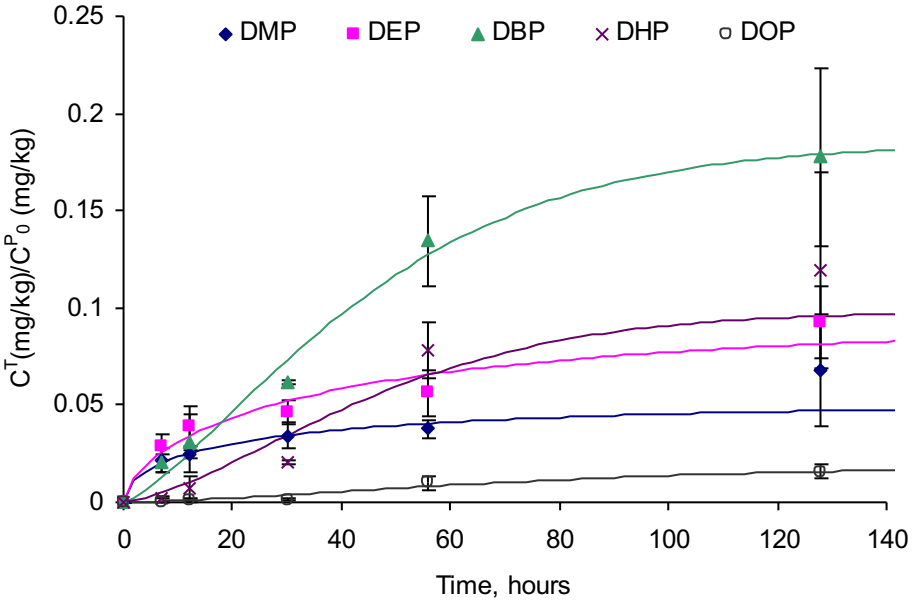


Transfer mechanisms in P&B: a) from the fibre matrix by direct contact; b) from the fibre matrix by indirect contact; c) from outer surface through the fibre matrix; and d) from the fibre matrix to the surrounding environment

Poças et al. Food Control 22 (2011) 303 - 312

Safety

- Characteristics of the migrant
  - Molecular weight and structure
  - Partition behaviour between P&B and food



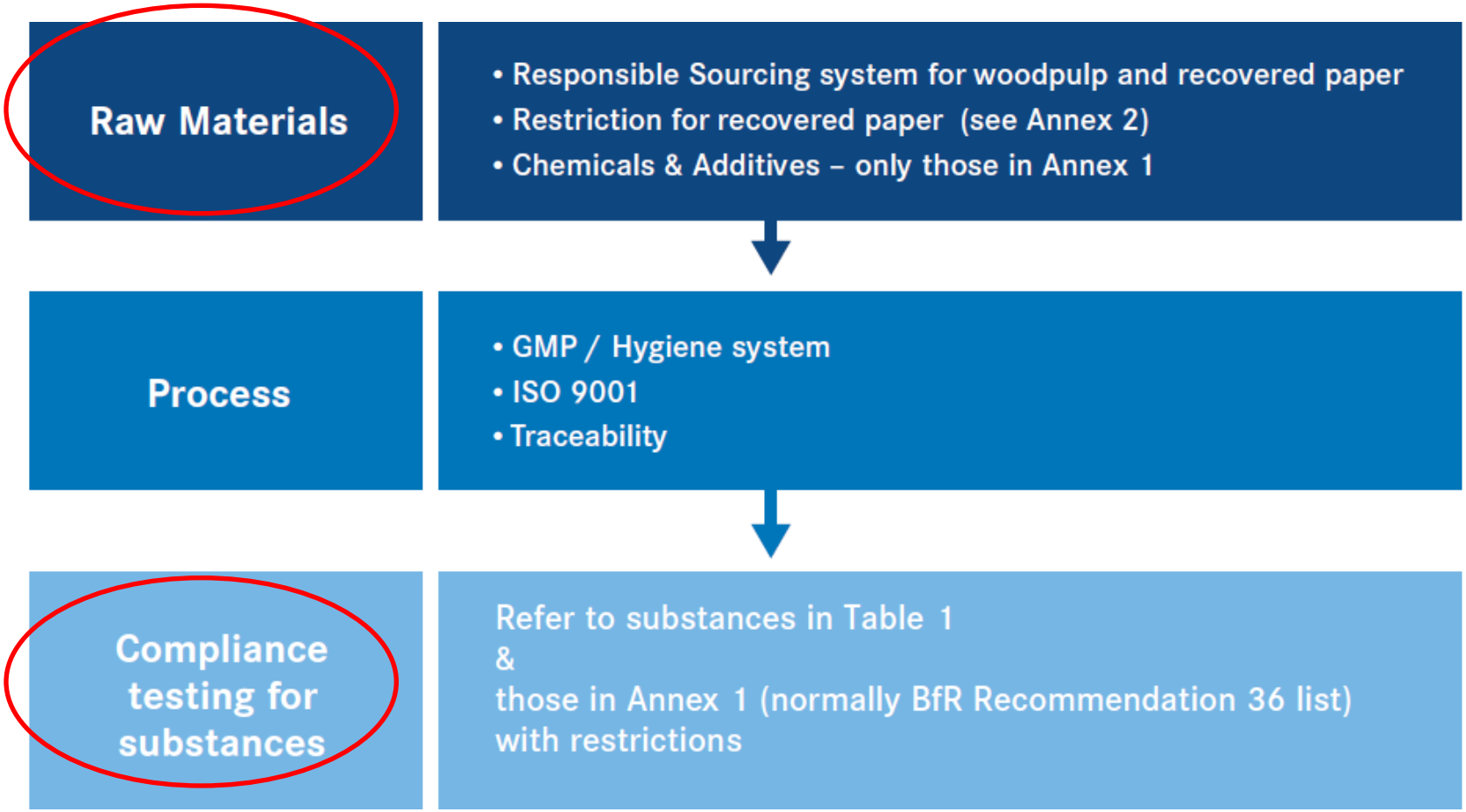
Migration of phthalates into Tenax at 23 C (three replicates): DMP (A); DEP (-); DBP (:); DHP (); DOP (o); *Poças et al. Food Control 22 (2011) 303 - 3*

Legislation. Europe

- Regulation (EC) No 1935/2004 (Article 3):
  - "Materials and articles, made of P&B, shall be manufactured in compliance with GMP so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
    - endanger human health, or
    - bring about an unacceptable change in the composition of the food, or
    - bring about a deterioration in the organoleptic characteristics of the food."

Legislation. Europe

- Assessing Compliance



CEPI – Industry guideline for the compliance of paper and board materials and articles for food contact, 2012

Legislation. Europe

- Assessing Compliance – Chemicals and additives

BfR
Bundesinstitut für Risikobewertung

This is an unofficial translation. Only the German version is binding.

XXXVI. Paper and board for food contact

As of 01.10.2014

Preamble

1. This Recommendation is valid for single and multi-layered commodities (articles, materials) made of paper or paperboard which are intended to come into contact with or affect food-stuffs. It includes paper or paperboard which is intended to be used at temperatures up to 90 °C (holding and reheating of food). For the following listed special applications (e.g. higher temperature range) the respective special Recommendation has to be noted:

   - For paper that in its intended use will be subject to hot extraction (boil-in-bag packages, tea bags, hot filter papers), and for filter layers that in their intended use will be subject to extraction (filtration) Recommendation XXXVI/1 applies.

   - For paper, paperboard and board which comes into contact with or affects foodstuffs dur-ing baking Recommendation XXXVI/2 applies. This recommendation also applies for usage

Legislation. Europe

- Chemical testing

Table 1 – Purity Requirements

SUBSTANCE	LIMIT IN FOOD	TESTED IN PAPER & BOARD	REMARK
	SML (mg/kg food)	Limit	
Cadmium	-	0.5 mg/kg	#
Lead	-	3.0 mg/kg	#
Mercury	-	0.3 mg/kg	#
Pentachlorophenol	-	0.15 mg/kg	
Antimicrobial Substances	-	No release of substances in quantities which have an antimicrobial effect.	
4,4'-bis (dimethylamino)-benzophenone (Michler's ketone)	0.01 mg/kg (non-detectable)	0.0016 mg/dm²	# ⋆
4,4'-bis (diethylamino) benzophenone (DEAB)	0.01 mg/kg (non-detectable)	0.0016 mg/dm²	# ⋆
Azo colourants[4]	-	0.1 mg/kg as aromatic amine[5] (non-detectable)	#
Dyes and colourants[6]	-	no bleeding	#
Fluorescent Whitening Agents (FWAs)[6]	-	no bleeding	#
Polycyclic Aromatic Hydrocarbons (PAHs)	0.01 mg/kg (non-detectable)	0.0016 mg/dm² [7]	⋆
Di-n-butylphthalate (DBP)	0.3 mg/kg	0.05 mg/dm²	⋆
Diethylhexylphthalate (DEHP)	1.5 mg/kg	0.25 mg/dm²	⋆
Diisobutylphthalate (DiBP)	0.3 mg/kg	0.05 mg/dm²	⋆
SUM DBP + DiBP	0.3 mg/kg	0.05 mg/dm²	⋆
Benzylbutylphthalate (BBP)	30 mg/kg	5 mg/dm²	⋆
Diisononylphthalate (DINP)	9 mg/kg	1.5 mg/dm²	⋆
Diisodecylphthalate (DIDP)	9 mg/kg	1.5 mg/dm²	⋆
Benzophenone	0.6 mg/kg	0.1 mg/dm²	⋆
SUM benzophenone+ hydroxy-benzophenone+ 4-methylbenzophenone	0.6 mg/kg	0.1 mg/dm²	
Diisopropylnapthalenes (DIPN)	-	As low as technically possible	⋆
Bisphenol A	0.6 mg/kg	0.1 mg/dm²	# ⋆

3. This is from the BfR Recommendation (see Annex 1) and this exception does not replace the responsibility of the operator to ensure compliance, at all times, with Regulation 1935/2004, particularly Article 3.
4. Testing is only required for virgin fibre based papers if azo colourants are added to the paper
5. Sum of listed amines. Regulation (EC) No 1907/2006 Annex XVII Appendix 8 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF
6. Testing is only required for virgin fibre based papers if dyes/colourants/optical brighteners are added to the paper
7. Sum of listed PAH's . A method for PAH measurement is in preparation in CEN/TC172/WG3.

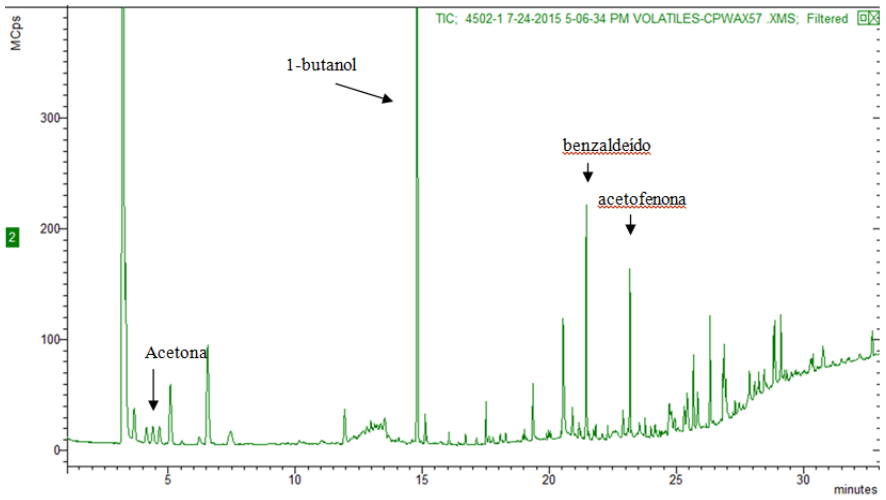
NOTE 1: *Testing for compliance with the limits in Table 1 should be carried out according to the testing methods and principles set out in Annex 3. Figure 3 provides a schematic representation of some elements of the determination of compliance.*

NOTE 2: *The limits quoted in Table 1 are from published sources, principally the BfR Recommendation XXXVI (Annex 1)and the Council of Europe Resolution ResAP (2002)1 and its Technical Document No. 3 (Ref. 4). The limits for phthalates are taken from Directive 2007/19/EC dated March 30, 2007 (DBP, DEHP, BBP, DINP, DIDP) and for DiBP from BfR Recommendation XXXVI (see Annex 1).*

CEPI – Industry guideline for the compliance of paper and board materials and articles for food contact, 2012

Legislation. Europe

- Screening methods
  - Chemical testing
  - Biological testing



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EXPLORATORY WORKSHOP

Workshop Booklet

Biological Testing of
Food Contact Materials

29 and 30 November 2010, Brussels, Belgium

A&I materials

- Legislation and guidance

EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E- Safety of the Food chain

E6- Innovation and sustainability

EU Guidance to the Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.

VERSION 1.0

A&I materials

- Definitions

1.1 Active materials and articles

1.1.1 ***Definitions***

Regulation (EC) No 450/2009 includes the following definitions:

- **'active materials and articles'** means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate **components** that would release or absorb substances into or from the packaged food or the environment surrounding the food;
    - 'releasing active materials and articles' are those active materials and articles designed to deliberately incorporate components that would release substances into or onto the packaged food or the environment surrounding the food;
    - 'released active substances' are those substances intended to be released from releasing active materials and articles into or onto the packaged food or the environment surrounding the food and fulfilling a purpose in the food.

1.2.1 ***Definitions***

- **'intelligent materials and articles'** means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

Intelligent packaging systems provide the user with information on the conditions of the food. The information provided shall be reliable and correct. In contrary to active components, intelligent components do not have the intention to release their constituents into the food. The intelligent component may be positioned on the outer surface of the package and may be separated from the food by a functional barrier. The functional barrier concept is explained in the part 1.3.

A&I materials

- Definitions and examples

Types of packaging or components that fall under the definition	Types of packaging or components that do NOT fall under the definition
Absorbing / scavenging systems	
Oxygen scavenger as active component Applications of oxygen scavengers could be in packaged pasta, milk powder, biscuits, etc. These scavengers are usually in the form of sachets. They scavenge or capture residual oxygen from inside the packaging (from the environment surrounding the foodstuff or from the foodstuff itself) to reduce exposure to oxygen. Exposure to oxygen may result in microbiological growth on the food, chemical changes to the food, etc. An oxygen scavenger is meant to reduce these effects thereby prolonging the shelf-life of the foodstuffs.	**Polymers exerting the function of "Active Oxygen Barrier"** Applications are for example PET incorporated with an oxygen scavenger to prevent the permeation of oxygen through the PET. The substance can be incorporated into the primary packaging (e.g. into bottle wall). The oxygen scavenger functions as an active barrier that should prevent the permeation of oxygen through the PET bottle. If the role of the oxygen absorber is to scavenge any oxygen and prevent it from permeating from the environment outside the bottle through the bottle wall into the food or the environment surrounding the food, it is not covered by the definition of active material or article. In the case that the internal oxygen is absorbed too, but such an effect is unintentional and rather minimal, it is not considered as an active packaging under Regulation (EC) No 450/2009. If there is an intentional effect, the application is covered by the definition and it should be declared and proven in the application.
Liquid absorbing polymers as active component Polymers such as cross-linked polyacrylates and/or methacrylates with an absorbing function as active component in a packaging are covered by the scope of active materials. They are intentionally designed to absorb moisture from the food. They may be used in the form of granules or fibres e.g. in pads composed of polymeric fibres, combined or not with cellulose, such as polyester, polypropylene, etc. or in trays made of expanded polystyrene.	**Pads composed of 100% natural cellulose with an absorbing effect** Cellulose pads may be used as moisture absorbing pads. Absorber pads made of pure cellulose fibres are not considered as active components in a packaging. Although they are intentionally used to absorb, they are not designed to **deliberately incorporate components** that would absorb substances from the packaged food or the environment surrounding the food. It is the natural structure of pure cellulose fibres that creates the absorbing effect and not intentionally incorporated substances or components. 100% cellulose pads are regarded as paper.
deterioration caused by micro-organisms and/or to protect against growth of pathogenic micro-organisms.	
A packaging application in which a preservative is intentionally incorporated to be released into the food **(category 3), is considered as an active material or article**. The anti-microbial is then the released active substance having a technological function on the food. It can be used if it is an authorised food preservative[3].	If the anti-microbial is incorporated onto or into materials and articles with the function of releasing the substance to the surface only **(category 2 – surface anti-microbials)** to exert a function on the plastic itself such as maintaining hygienic properties (by keeping only the surface free from anti-microbial growth), or used as a **processing anti-microbial (category 1)** and since the active ingredients are not intended to have a function on the food or the environment surrounding the food, these applications **are not considered as active materials or articles**. Surface anti-microbials are regarded a type of additives used in food contact materials. An example for category 2 is the surface of the refrigerator with silver salts marketed as improving the hygiene.

A&I materials - Safety evaluation

- Principles: risk assessment to be included in the Union list of active and intelligent substances
- Union list
  - > 50 registered
- Passive part vr active part
- Interaction between components
- Overall migration
- Specific migration/maximum quantity
- Potential to mislead the consumer on the condition of the food are illegal

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Innovation and Sustainability

Brussels,
D(2012) 14.06.2012

Register of substances for which a valid application for authorisation was submitted under Regulation (EC) No 450/2009[1]

COST Action FP1405
Active and intelligent fibre-based packaging – innovation and market introduction (ActInPak)

ActInPak is a pan European (COST) network of the leading experts in active and Intelligent packaging of over 50 institutes and universities of 28 different countries.

The main objective is to develop a knowledge-based network on sustainable, active and intelligent fibre-based packaging in order to overcome current technological, industrial, and social limitations that hinder the wide deployment of existing and newly developed solutions in market applications.

http://www.cost.eu/COST_Actions/fps/Actions/FP1405

http://www.actinpak.eu

https://www.linkedin.com/groups/COST-FP1405-ActInPak-8254568/about

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Thanks for your attention

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