Food safety and food contact legislation

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COST FP1405
ACTIVE AND INTELLIGENT FIBRE-BASED PACKAGING – INNOVATION AND MARKET INTRODUCTION

April, 5th 2016

COST
EUROPEAN COOPERATION IN SCIENCE AND TECHNOLOGY

COST is supported by the EU Framework Programme Horizon 2020

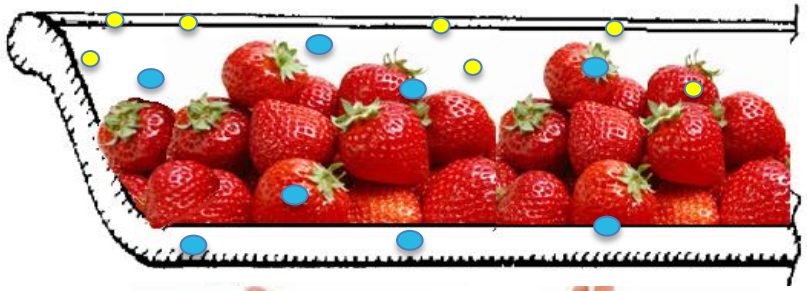
A well-known definition….

- '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**
  - (EU Reg. 450/2009)

Food as a target

FOOD QUALITY AT THE CENTER OF THE AP DESIGN PROCESS



mould growth control

off-flavor adsorbtion

respiration rate control…

If the GOAL is the **SHELF LIFE EXTENTION**, an ACTIVE SOLUTION SHOULD ACT REDUCING THE RATE OF THE **MAIN FOOD DECAY EVENT**

..BUT it is not enough

Safety first!!!

ACTIVE PACKAGING SOLUTIONS ARE CONSIDERED AS FOOD CONTACT MATERIALS….thus…

THEY SHALL ONLY BE AUTHORIZED IF IT IS DEMONSTRATED THEY DO NOT PRESENT RISKS TO HUMAN HEALTH (article 8, Reg 1935/2004)

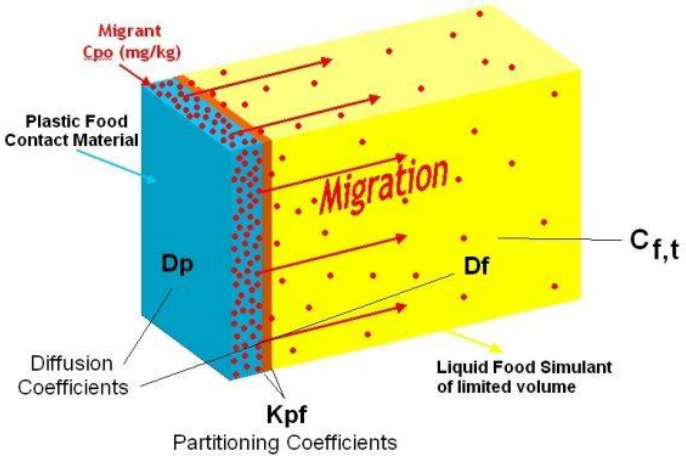
Migration&Food Safety

MIGRATION is the mass transfer from an external source into food by sub-microscopic processes

May impact food in two ways (Bradley)

1 **Safety** – migration of harmful substances

2 **Quality** – migration of substances which impart taint or odour



THE MIGRATION OR DIFFUSION PHENOMENA FROM PACKAGING INTO FOODS MUST BE CONTROLLED, REDUCED AND POSSIBLY FORESEEN

..BUT it is not enough

Safety first!!!

L 338/4 EN Official Journal of the European Union 13.11.2004

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 2004

on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

SAFETY OF FOOD CONTACT MATERIALS REQUIRES **EVALUATION** AS **CHEMICALS CAN MIGRATE** FROM MATERIALS INTO FOODS.

The materials should be **manufactured in compliance with European Union (EU) Regulations**, including good manufacturing practices (Reg 2023/2006), so that any **potential transfer** to food **does not raise safety concerns**, **change in composition of the food in an acceptable way** or **have adverse effects on quality and sensorial properties** (taste/odour)

from Art.3 **Reg. CE 1935/2004**

http://www.efsa.europa.eu/en/topics/topic/active_intelligent_packaging

..Safety first…

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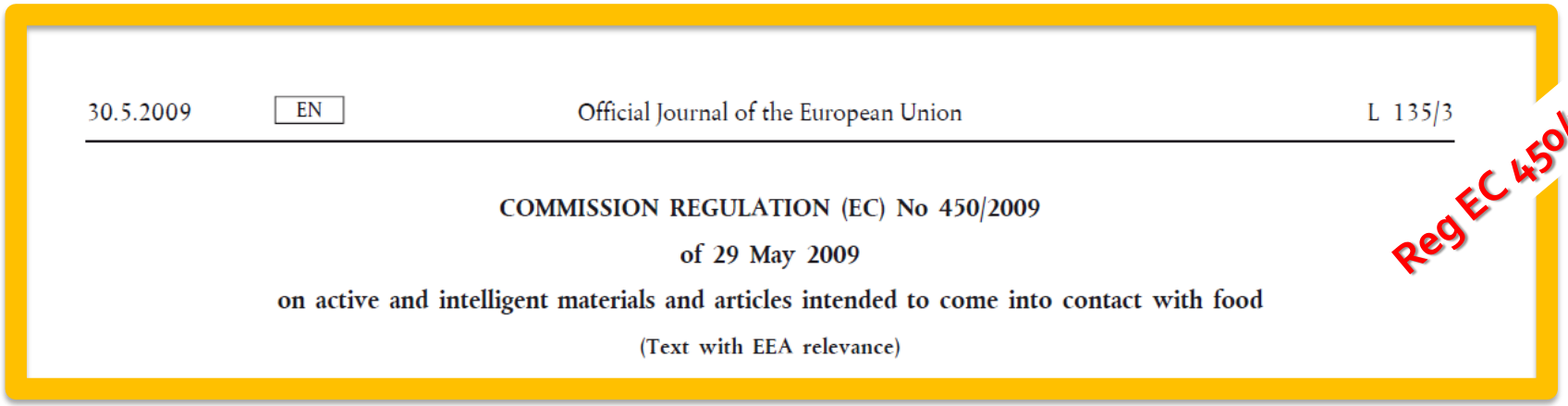
Reg EC 1935/2004

FRAMEWORK REGULATION
EC 1935/2004 → **VALID FOR ALL THE FOOD CONTACT MATERIALS & ARTICLES**

ACTIVE AND INTELLIGENT PACKAGING ARE INCLUDED IN ITS FIELD OF APPLICATION. In 2009 a SPECIFIC MEASURE (Reg EC 450/2009) was adopted



30.5.2009 EN Official Journal of the European Union L 135/3

COMMISSION REGULATION (EC) No 450/2009

of 29 May 2009

on active and intelligent materials and articles intended to come into contact with food

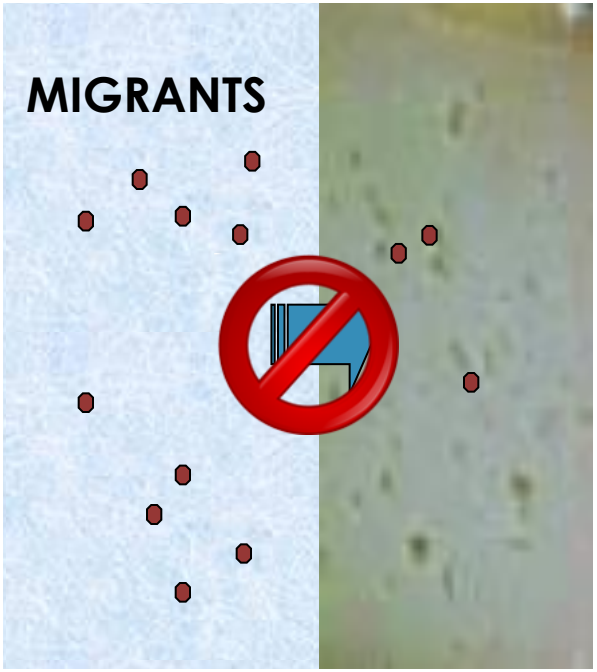
(Text with EEA relevance)

Reg EC 450/2009

Is there a contradiction?

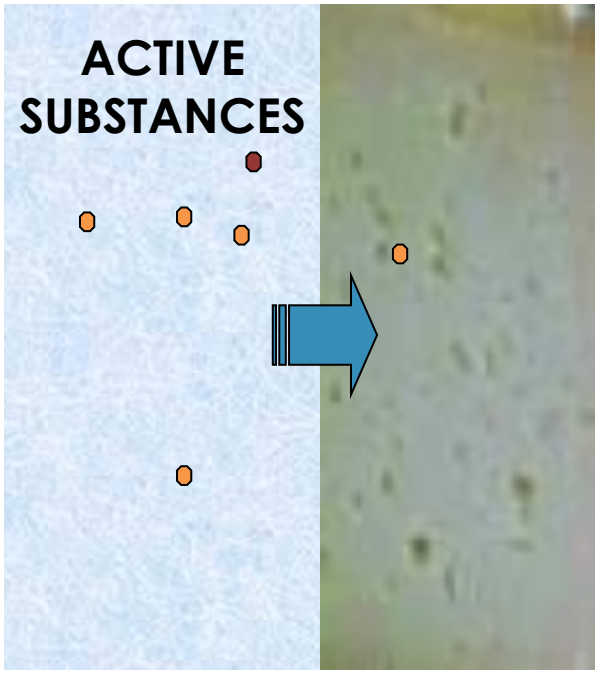
TRADITIONAL PACKAGING:

Migration of ADDITIVES:
REDUCED



ACTIVE PACKAGING:

Migration OF ACTIVE SUBSTANCES:
ENHANCED



A right distinction….for the purpose of safety

- PASSIVE part

Means all material(s) and article(s) **into which** the active component is added or incorporated (such as the primary packaging material into which it is incorporated).

- ACTIVE substance

Means **individual substance** or a **combination of individual substances** which cause the **active function** of a material or article, including the products of *in situ* reaction of these substances.

LEGAL REQUIREMENTS OF THE PASSIVE PART

.....A SHORT MEMORANDUM

Safety of PASSIVE components

PASSIVE PARTS SHOULD BE COVERED BY THE SPECIFIC COMMUNITY (i.e. plastics) or national legislation applicable (i.e. paper and paperboard, adhesives, inks, etc)

i.e. PLASTICS (Reg EU 10/2011):

PRINCIPLE OF INERTNESS

Overall migration limit (OML)

10 mg/dm² or 60 mg/kg

+

Sensorial inertness

Reg EU 10/2011+

Art.3 Reg 1935/2004

PRINCIPLE OF SAFETY

Substances authorized under Regulation EU 10/2011 on plastic materials

Specific migration limit (SML) and/or Maximum permitted quantity (QMA)

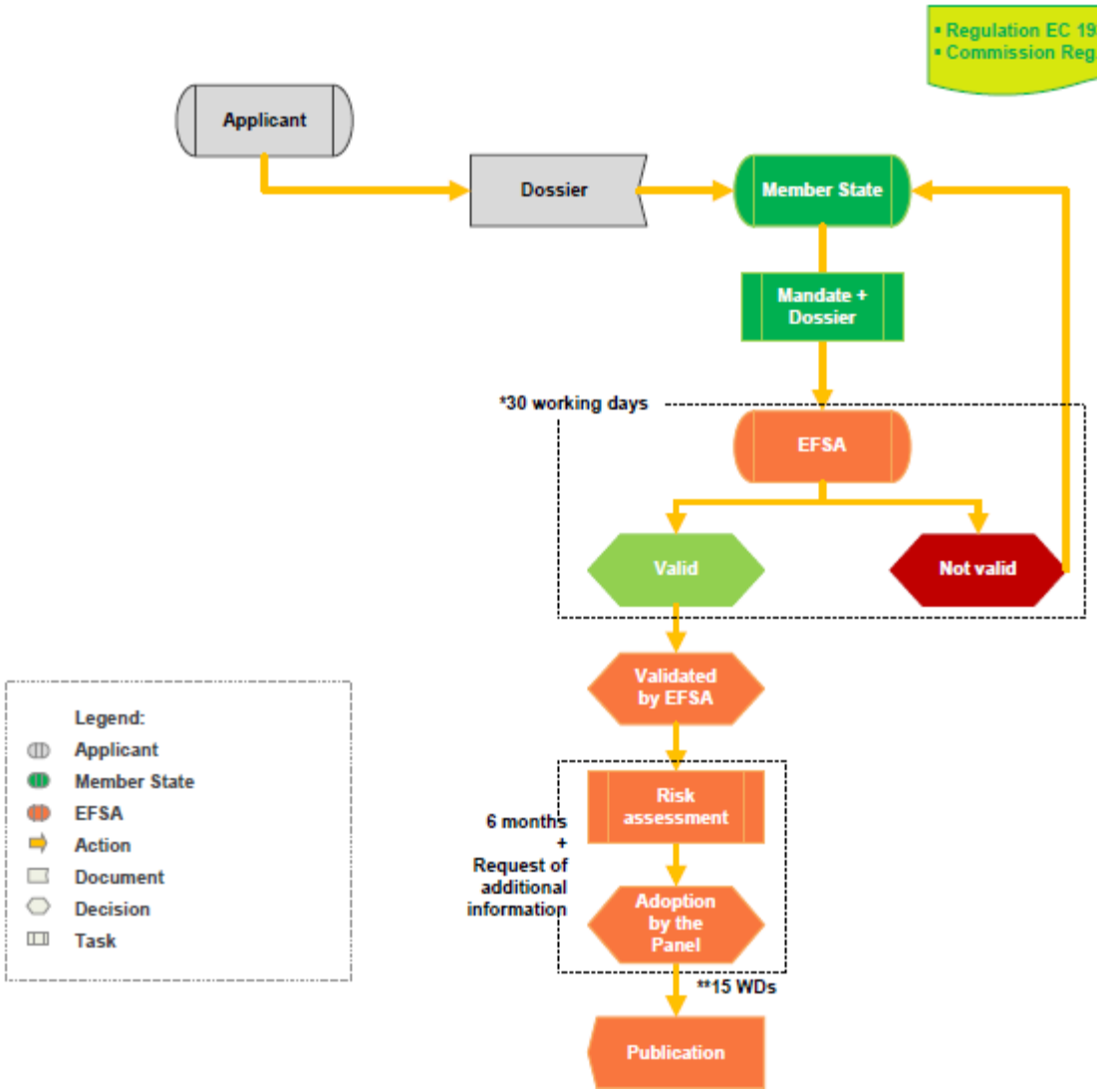
SEE Union List of authorized substances (Reg EU 10/2011)

IF THE SUBSTANCE IS NOT AUTHORIZED:

Specific authorisation of substances

1. EFSA evaluation – risk assessment
2. Commission – risk management decision

Application helpdesk ..authorization for new substances



The application procedure is described in Regulation EC 1935/2004.

The **technical dossier** of an application submitted under Regulation EC 1935/2004 must be compiled according to EFSA's guidance.

Applications should be submitted to the national competent authority of a Member State, which will transmit your application to EFSA

Source:
http://www.efsa.europa.eu/en/foodcontactmaterials/appworkflowfoodcontactmaterialsapplications.htm

Safety of PASSIVE components

PASSIVE PARTS SHOULD BE COVERED BY THE SPECIFIC COMMUNITY (i.e. plastics) or national legislation applicable (i.e. paper and paperboard, adhesives, inks, etc)

i.e. PAPER&PAPERBOARD

PRINCIPLE OF INERTNESS

Sensorial inertness

Art.3 Reg 1935/2004

National legislation

PRINCIPLE OF SAFETY

Substances listed in

Council of Europe Resolution ResAP (2002) and its Technical Document

National legislation

....

BfR Recommendation XXXVI

LEGAL REQUIREMENTS OF THE ACTIVE MATERIALS

.....A SHORT MEMORANDUM

Legal requirements

Regulation (EC) No 450/2009 is a specific measure that lays down specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.

The substance(s) responsible for the active and/or intelligent function of the material

should be evaluated

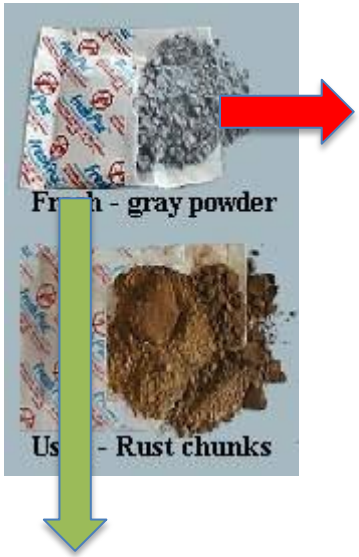
under the regulation (EC) No 450/2009.

Does the Community list already exist??
Which substances ??
By whom??
How ???

Only substances which are included in the '**Community list**' of authorized substances may be used in components of active and intelligent materials and articles.

Some examples…PASSIVE vs ACTIVE

O_2 SCAVENGER IN A SACHET

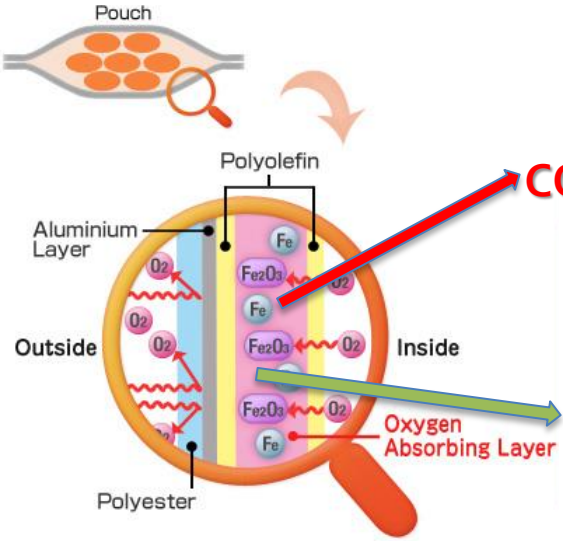


ACTIVE COMPONENT

Other substances that do not play a role in active function, belong to the passive part of the packaging

PASSIVE FILM

O_2 ABSORBER IN A PLASTIC FILM



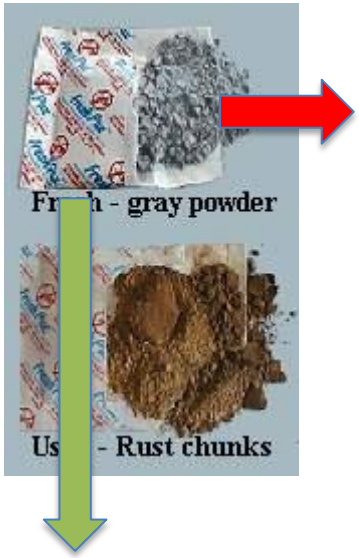
ACTIVE COMPONENT

PASSIVE FILM

If the role of oxygen absorber is to scavenge any oxygen and **PREVENT** it from permeating **from the environment outside the package through the package wall into the food or the environment surrounding the food, it is NOT considered an ACTIVE PACKAGING under Reg. EC 450/2009,** but a barrier enhancer

Some examples…PASSIVE vs ACTIVE

O_2 SCAVENGER IN A SACHET



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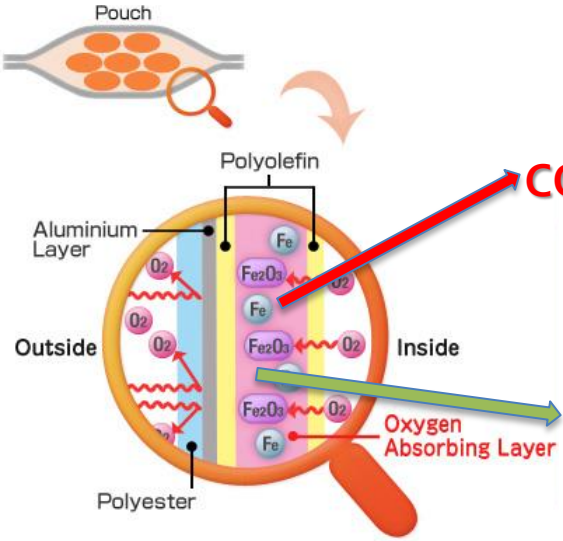


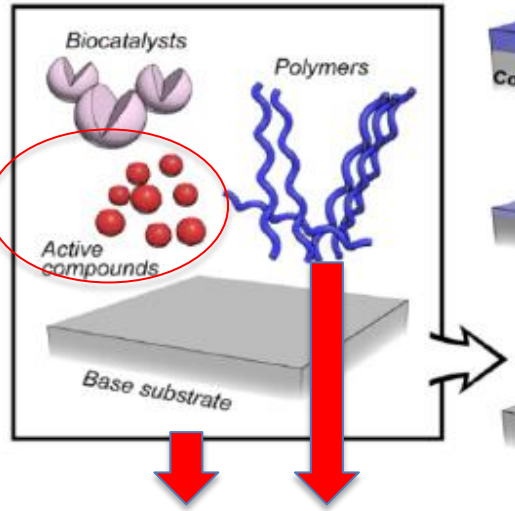
ACTIVE COMPONENT

PASSIVE FILM

If the internal O_2 is absorbed too but the effect is UNINTENTIONAL or LIMITED, **it is NOT considered an ACTIVE PACKAGING**

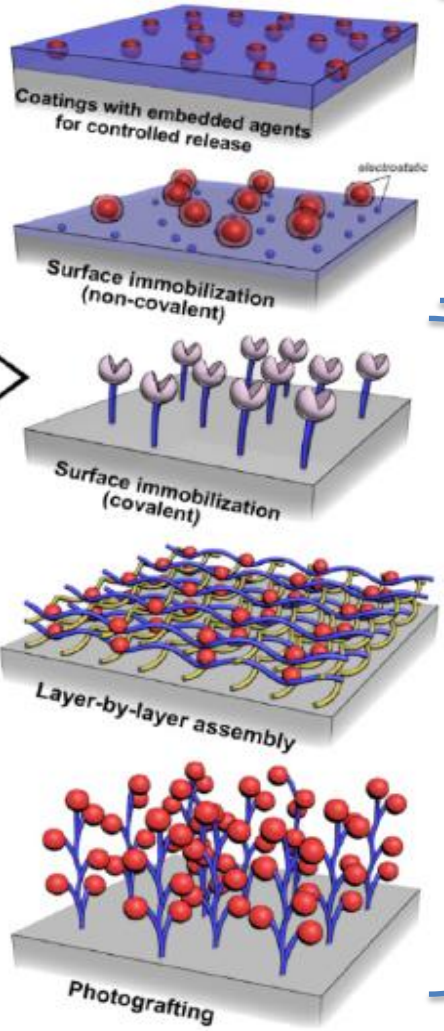
If there is an INTENTIONAL EFFECT on FOOD or ENVIRONMENT around it, **it is considered an ACTIVE PACKAGING**

Some examples…PASSIVE vs ACTIVE



ACTIVE COMPONENT

PASSIVE PARTS



ANTIMICROBIAL IN A COATING

ACTIVE: if it's released from the material

ANTIMICROBIAL IMMOBILIZED AND INCORPORATED BY GRAFTING

ACTIVE: If deliberately influences the conditions of food without intentional migration

Bastarrachea et al., 2015. Coatings 2015, 5, 771-791

Some examples…PASSIVE vs ACTIVE

ANTIMICROBIAL IN A MULTILAYER FILM

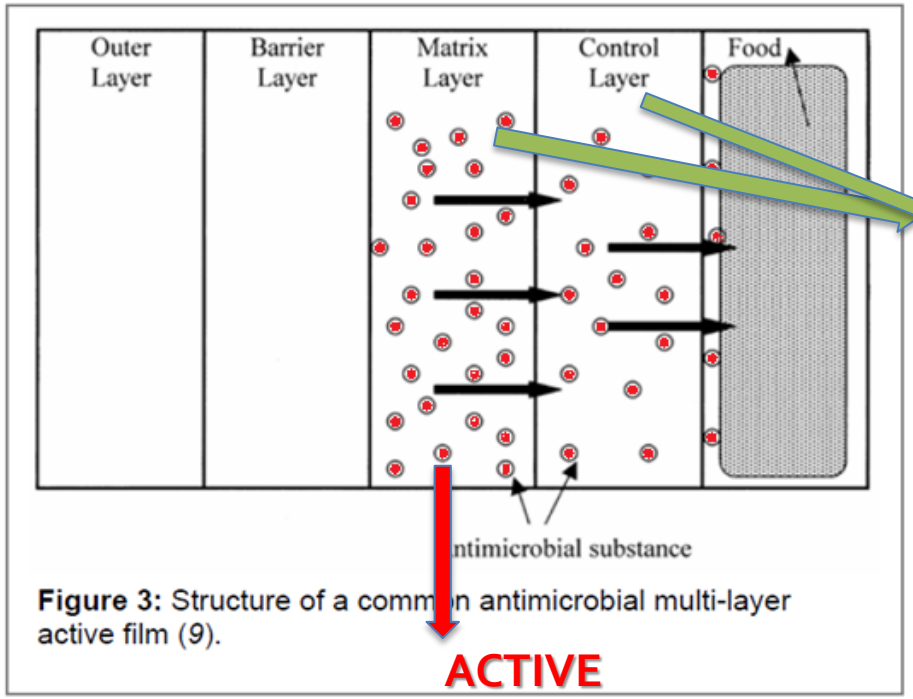


Figure 3: Structure of a comm n antimicrobial multi-layer active film (*9*).

PASSIVE FILMS

ACTIVE COMPONENT
Because it's released from the material into food

(Ozdemir and Floros, 2004)

WHICH SUBSTANCES are considered ACTIVE….??

ANTIMICROBIAL SUBSTANCES

- EXTRACTS
- PRESERVATIVES
- SURFACE ANTIMICROBIALS
- PROCESS ANTIMICROBIALS

Used as components in manufacture of food contact material to maintain it free from microbial contamination during handling process or storage

No antimicrobial function is exerted on final material and **ON FOOD**

NO ACTIVE SUBSTANCE

WHICH SUBSTANCES are considered ACTIVE….

Some examples in antimicrobial field….

ANTIMICROBIAL SUBSTANCES

- EXTRACTS
- PRESERVATIVES
- SURFACE ANTIMICROBIALS
- PROCESS ANTIMICROBIALS

Keep the surface of the food contact material free from microbial contamination.

Antimicrobials do not have **ANY TECHNOLOGICAL EFFECT ON FOOD** because they are not intended to be transferred to food

NO ACTIVE SUBSTANCE

see **Biocides Regulation (EU) No 528/2012 and (EU) No 1062/2014**

WHICH SUBSTANCES are considered ACTIVE….

ANTIMICROBIAL SUBSTANCES

- EXTRACTS
- PRESERVATIVES
- SURFACE ANTIMICROBIALS
- PROCESS ANTIMICROBIALS

Have **TECHNOLOGICAL EFFECT ON FOOD:** they can control the microbial growth in a food extending the shelf life.

If it is intentionally incorporated to be **RELEASED** into food

ACTIVE SUBSTANCES

WHICH SUBSTANCES are considered ACTIVE….

ANTIMICROBIAL SUBSTANCES

- EXTRACTS
- PRESERVATIVES
- SURFACE ANTIMICROBIALS
- PROCESS ANTIMICROBIALS

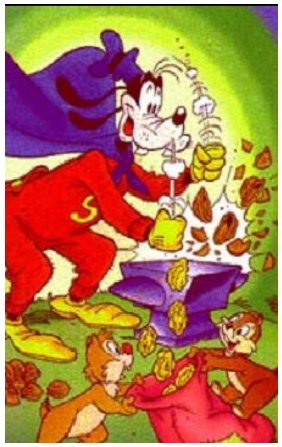
Extracts from plants, microorganisms or animal origin.

They can be RELEASED, with **TECHNOLOGICAL EFFECT ON FOOD**

ACTIVE SUBSTANCES

Question: WHICH SUBSTANCES CAN BE CONSIDERED ACTIVE?

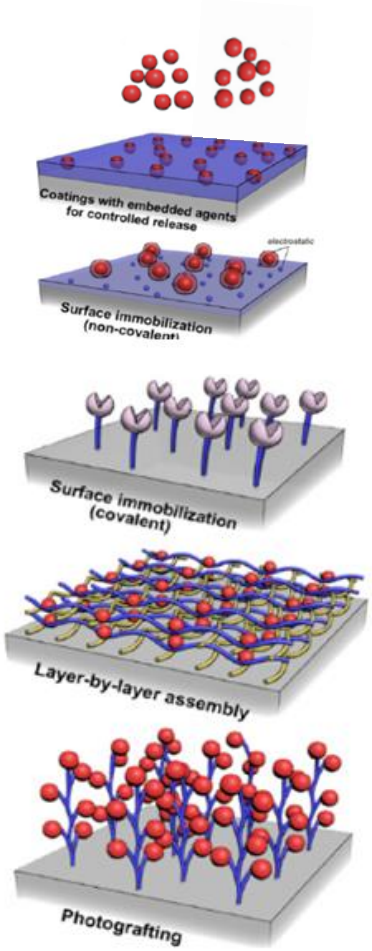
Answer: ONLY THOSE SUBSTANCES THAT HAVE A TECHNOLOGICAL EFFECT ON FOOD QUALITY AND SAFETY



YES, BUT …IN DETAIL…WHICH SUBSTANCES?? …AND…WHICH OF THEM CAN BE EVALUATED UNDER REG EU 450/2009 FOR THE CREATION OF THE UNION LIST?

WHICH SUBSTANCES are considered ACTIVE….

ACTIVE substances that have technological effects on the food



a) PRESERVATIVES/FOOD ADDITIVES/ ENZYMES

Should be used under relevant EU or national provisions.

Commission Regulation EC 1333/2008 + **Reg 1129/2011** and **Reg 1130/2011** that amend Annex II and III

Legislation on food additives, enzimes and flavouring

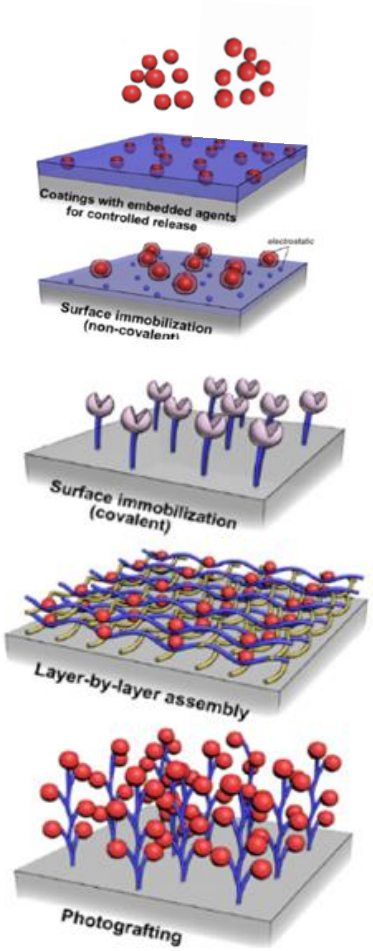
→ With applicable restrictions and conditions

New substances (new food additives or a request for an extension of use) are subject to an **authorization procedure laid down in Reg EU 234/2011**

They **will not be included** in the **UNION LIST** of active and intelligent materials and articles as they fall under the relevant EU or national provisions for their use in the food

WHICH SUBSTANCES are considered ACTIVE….

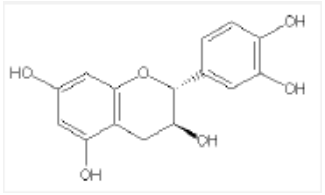
ACTIVE substances that have technological effects on the food

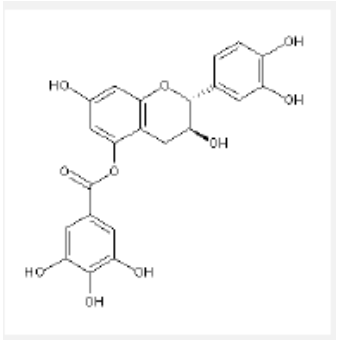


b) EXTRACTS (i.e extract of rosemary, nisin produced by fermentation… etc)

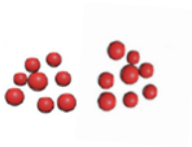
If the substances function as preservatives, they have to comply with the existing legislation on food additives, enzimes and flavouring

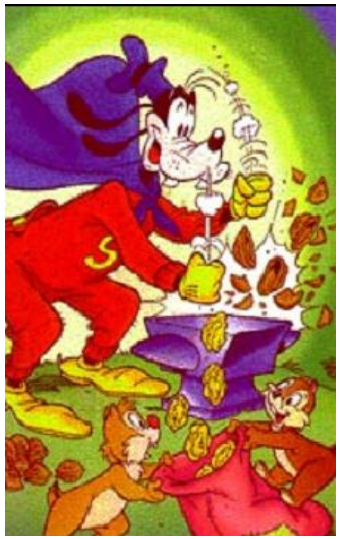
New substances (new food additives or a request for an extension of use) are subject to an **authorization procedure laid down in Reg EU 234/2011 and not under Reg 450/2009**





WHICH SUBSTANCES are considered ACTIVE….





c) OTHER SUBSTANCES (THE MOST IMPORTANT FOR US!!!!!)

If the active function implies **INTERACTION** between different substances leading to the enhancement of the specific function (i.e. antioxidant, scavenger, etc) or the **GENERATION of new substances** responsible for that specific function, thus these substances (i.e. the **COMPLEX**) are considered as «active substances».

These substances (COMBINATION OF SUBSTANCES) are subject to **authorization under Reg EU 450/2009.**

This means that a **RISK ASSESSMENT** will be carried out by EFSA to support the authorization process.

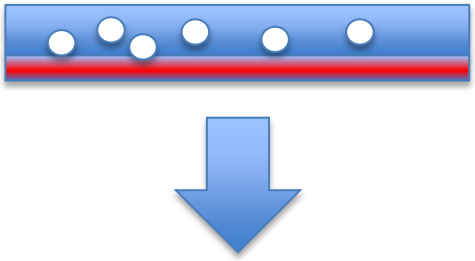
After the positive opinion of EFSA and the authorization by the EU Commission, they **will be included** in the **UNION LIST** of active and intelligent materials

Few words about intelligent packaging

EXAMPLE

Packaging X is an intelligent packaging, a tray with a time-temperature indicator attached. The time temperature-indicator is on the **non-food contact surface** of the packaging, separated from the food with a **functional barrier**.

If intelligent components are on the non-food contact surface of the packaging and they are separated from the foodstuff by a **FUNCTIONAL BARRIER**, the migration of **non-authorised substances** from the intelligent component into the food shall not be detectable.



The maximum tolerated migration level is then 0,01 mg substance per kg food.

OK

NO authorization. Only appropriate documentation about functional barrier performances

KO

NO application of FUNCTIONAL BARRIER. Request of AUTHORIZATION (Reg 450/2009)

Anyway……

BEHIND A FUNCTIONAL BARRIER

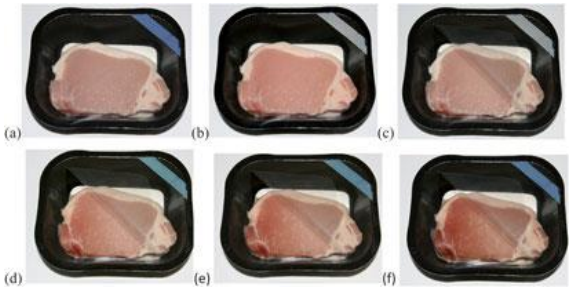
substances classified as ‘mutagenic’, ‘carcinogenic’, or ‘toxic to reproduction’

substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale

Few words about intelligent packaging

EXAMPLE

Packaging X is an intelligent packaging, a film with a time-temperature indicator **INCORPORATED** in the **FOOD CONTACT LAYER**.



In contrary to active components, intelligent components are not intended to release their constituents into the food

application for risk assessment and authorization under (EU) No 450/2009 should be submitted to be included in the Union list.

Few words about substances in nanoform

New technologies that *engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale*, for example, nanoparticles, **should be assessed on a case-by case** basis as regards their risk until more information is known about such new technology.

Therefore, they are not covered by the functional barrier concept.

Table 2: Main parameters, according to EFSA Guidance on nanoscience and nanotechnologies (EFSA Scientific Committee, 2011a), for characterisation and identification of nanomaterials used in FCM, present in the FCM and possibly migrating from the FCM

Parameter	Description
Particle size (primary/secondary)	Information on primary particle size, size range and number-size distribution (indicating batch-to-batch variation, if any). The same information is needed for secondary particles (e.g. agglomerates and aggregates), if present.
Physical form and morphology	Information on the physical form and crystalline phase/shape. The information should indicate whether the material is present in a particle, tube or rod shape, crystal or amorphous form and whether it is in free particulate form or in an agglomerated/aggregated state, as well as whether the preparation is in the form of a powder, solution, suspension or dispersion.
Chemical reactivity/catalytic activity	Information on relevant chemical reactivity or catalytic activity of the material and of any surface coating.
Photocatalytic activity	Information on photocatalytic activity of relevant materials used in food packaging, coatings and printing inks and on internal reactions.

How submit info for authorization

- In August 2009 EFSA published guidelines on the submission of dossiers for the safety assessment of Active&Intelligent Packaging

- !!! Specification of which aspects EFSA takes into account when assessing the safety of these substances and the type of data needed to conduct the assessment

* CEF panel: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

How submit info for authorization

European Food Safety Authority

The EFSA Journal (2009) 1208

Opinion of the Panel on
food contact materials, enzymes, flavourings and processing aids (CEF)

Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food

Question number EFSA-Q-2005-041

Adopted on 21/07/2009

AFTER PUBLIC CONSULTATION

I call deadline: 14 February 2011

How submit info for authorization

- The approach of CEF panel*:

- EVALUATE SAFETY ON THE BASIS:
  - the migration of the active and/or intelligent substance(s)
  - the migration of their possible degradation and/or reaction products
  - the toxicological properties of constituents

* CEF panel: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Info to be supplied with the application

1. SUMMARY DOCUMENT
2. THE ADMINISTRATIVE PART
3. **THE TECHNICAL DOSSIER**

B. IDENTITY OF THE ACTIVE/INTELIGENT SUBSTANCE
(chemical name IUPAC, CAS number…., proportion of constituent in the mixture……)

C. PHYSICAL-CHEMICAL CHARACTERISTICS OF THE SUBSTANCE
(physical state, melting point, stability, decomposition temperature, unintended reaction or breakdown products originated during the manufacturing process, reactions with the passive part….)

D. MANUFACTURING PROCESS OF THE SUBSTANCE AND MATERIALS AND ARTICLES
(process of production, incorporation, maximum percentage of the active substance in the food contact material)

E. INTENDED USE OF ACTIVE/INTELLIGENT PACKAGING
(food categories…worst case conditions of use…)

F. EXISTING AUTHORIZATION

Info to be supplied with the application

3. THE TECHNICAL DOSSIER

G. MIGRATION DATA

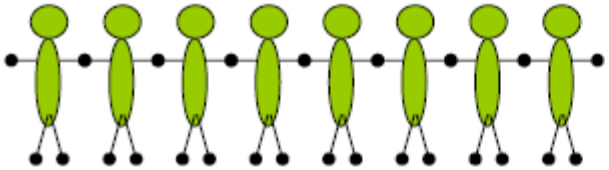
Migration data of **active and/or intelligent substances** and, if any, **impurities**, **reaction products** and **degradation products (OFTEN REFERRED TO NIAS)**, should be provided using **where appropriate conventional migration tests**, or **dedicated migration/evaluation tests** in foods or simulants with demonstrated adequacy for the intended/recommended conditions of use.

H. TOXICOLOGICAL DATA

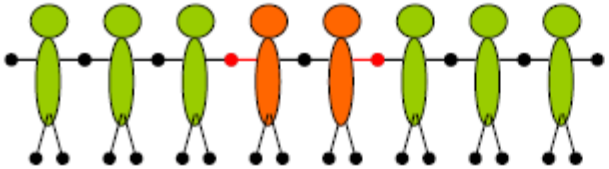
Toxicological data on each substance and if relevant on **its (their) degradation products** and **any identified reaction by-products**, should be provided. As a general principle, **the extent of toxicological studies needed will be dependent on the level of exposure through migration**.
The greater the exposure, the more toxicological information will be required

a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

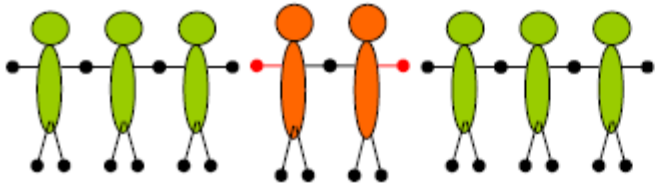
Be careful to **NIAS**!!



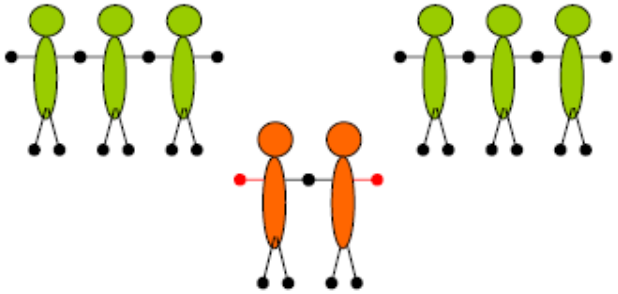
Active polymer (absorbing system)



The polymer **reacts** with residual O2 present in the package



The degradation products of the polymer can **migrate into food**

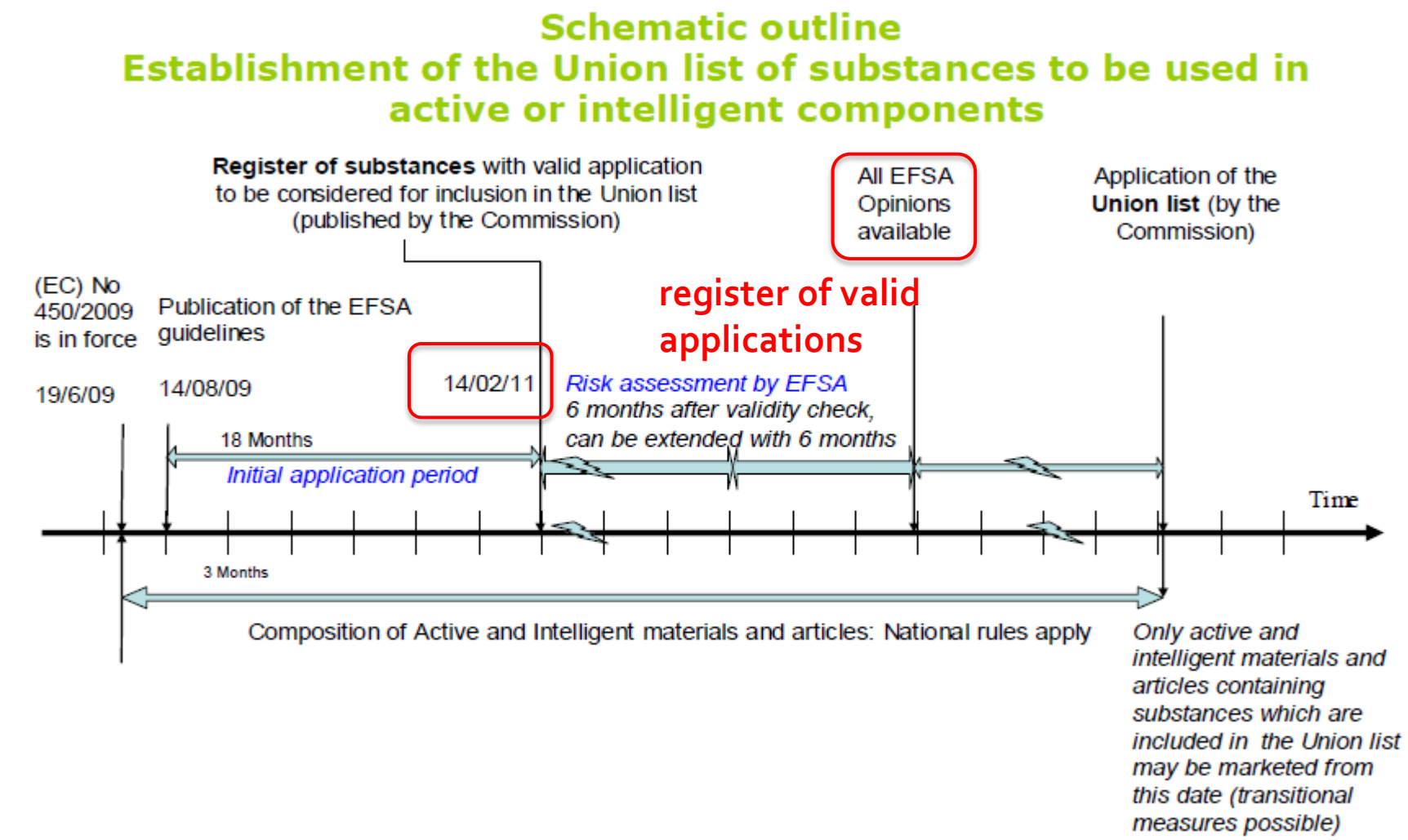


THE NEED OF A RISK ASSESSEMENT AS REQUESTED BY REGUALTION

SOURCE: Food safety linked to chemical contamination through packaging materials: EFSA's guidelines for active and intelligent packaging (Feigenbaum, Spyropoulos, Joly, 2008. CCM Conference, Bonn)

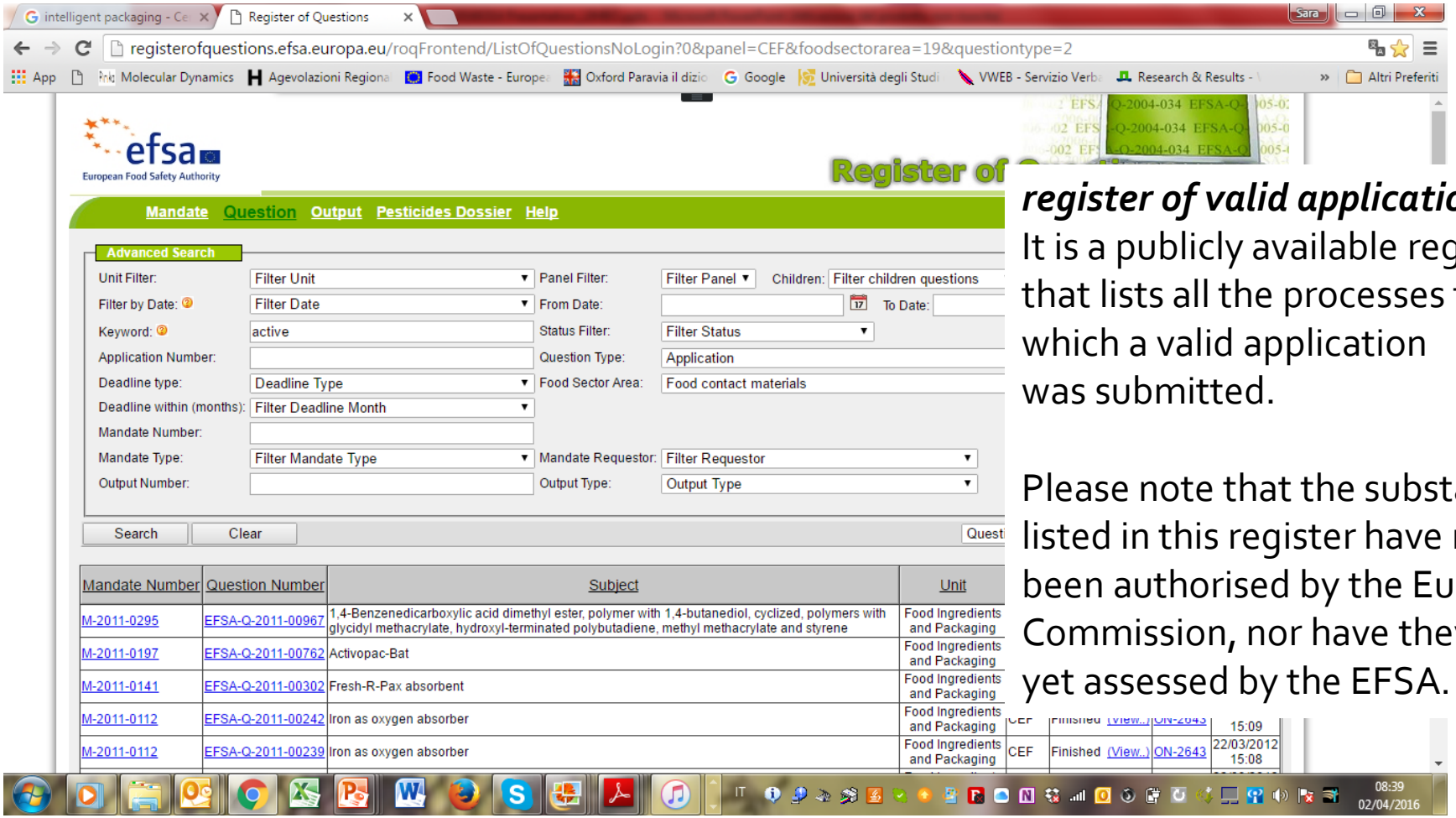
Timeframe*

Annex I



* EU Guidance to the Commission Regulation (EC) 450/2009

Register of valid applications



register of valid applications
It is a publicly available register that lists all the processes for which a valid application was submitted.

Please note that the substances listed in this register have not yet been authorised by the European Commission, nor have they been yet assessed by the EFSA.

http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?o&panel=CEF&foodsectorarea=19&questiontype=2

SOME EFSA opinions...

SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of a time-temperature indicator system, based on Carnobacterium maltaromaticum and acid fuchsin for use in food contact materials[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2, 3]

indicator on the packaging of chilled food. The micro-organism, the indicator and a nutritive medium gel are incorporated in a multilayer plastic sachet glued onto the outer layer of the food package. All the substances constituting the system, with the exception of acid fuchsin, are authorised as food additives, food colorants or novel food ingredients, or are an enzymatic digest of edible protein sources and yeast edible extract. Specific migration of acid fuchsin was estimated to be less than 7 x 10^{-9} mg/kg food. Acid fuchsin elicited a positive response in a bacterial gene mutation assay and a negative response in an *in vitro* micronucleus assay. Given the lack of *in vivo* studies, the genotoxicity potential of acid fuchsin cannot be ruled out. However, the Panel noted that the layer of the plastic sachet in contact with food contact articles behaves as a barrier which prevents any release of its content (including acid fuchsin), and that the sachet is stuck onto the outer layer of the packaging, hence is not in contact with the food. Thus no exposure to the substances constituting the system from the consumption of the packed food is expected under the intended conditions of use. Therefore, the Panel concluded that the substances of the intelligent system, *C. maltaromaticum* and acid fuchsin, do not raise a safety concern for the consumer when used in a plastic sachet which prevents any migration from the system into food and which is stuck onto the outer layer of the packaging of chilled food.

SOME EFSA opinions...

Scientific Opinion on the safety evaluation of the active substances, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride for use in food contact materials[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2, 3]

ABSTRACT

This scientific opinion of EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety evaluation of an iron based oxygen absorber, comprising polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride. This mixture is incorporated in polyethylene (PE) or polypropylene (PP) articles intended to be in contact with foodstuffs for hot fill/pasteurisation and/or long term storage at room temperature. For dried and fatty foods, direct contact with the materials is envisaged whereas other food types will be separated from the active material by a layer that does not contain the active components. All the substances constituting the oxygen absorber system have been evaluated and authorised for use as plastic food contact materials, as food additives or as food supplements. Based on migration results, the specific migration limits for iron, polyethyleneglycol, pyrophosphoric acid salts, phosphoric acid salts and sodium chloride, and the tolerable intake of phosphorus (phosphate) are not expected to be exceeded when the oxygen absorber system is used under the intended conditions of use, notably behind a layer not containing the active substance for contact with aqueous or acidic foods. Therefore, the CEF Panel concluded that the use of the substances, iron, polyethyleneglycol, disodium pyrophosphate, monosodium phosphate and sodium chloride do not raise a safety concern when used as oxygen absorbers incorporated in polyethylene and in polypropylene articles used for long time storage and/or hot fill up to 95 °C for several minutes in i) direct contact with dry and fatty foods and ii) indirect contact with aqueous or acidic foods, separated from the active material by a layer of at least 10 µm polyethylene or polypropylene that does not contain the oxygen absorber formulation.

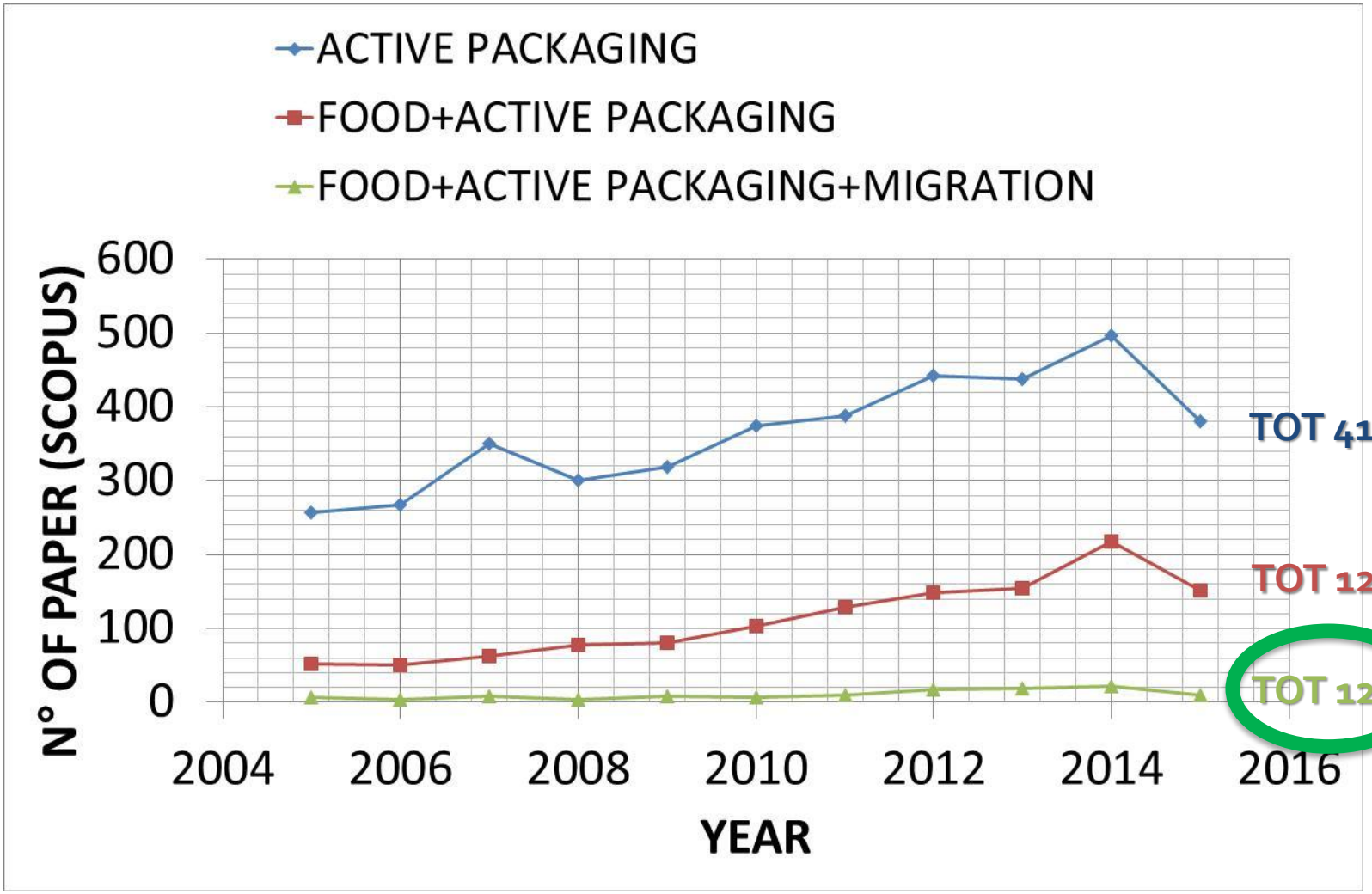
FINAL REMARKS

..from LEGISLATION some suggestions to ORIENT scientific research

and **VICE-VERSA**

…from SCIENTIFIC RESEARCH some suggestions to SUPPORT legislation

FINAL REMARKS: open issues



DATA from SCOPUS 2005-2015

The KEY-words of AP safety…

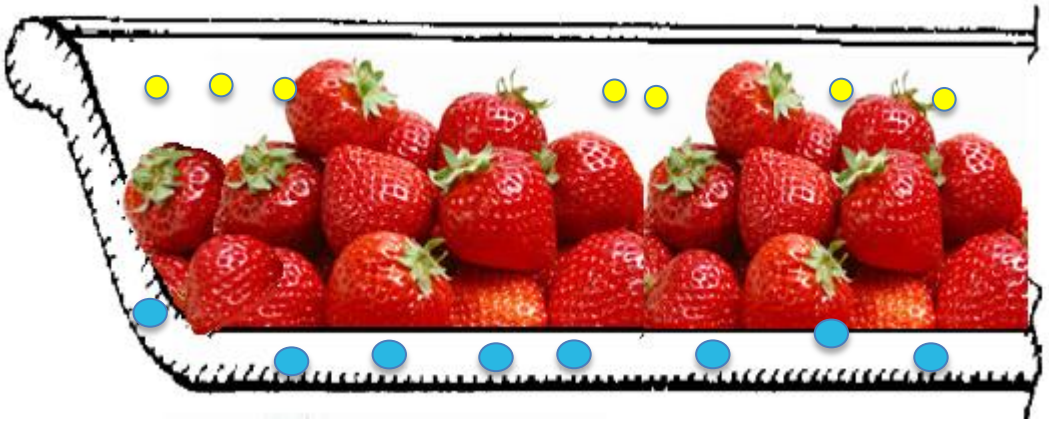
TESTING

MODELING

ANALYTICAL METHODS

MIGRATION

SIMULANTS



RISK ASSESSMENT

TOXICOLOGY

NON INTENTIONALLY ADDED SUBSTANCES

CONSUMER EXPOSURE

NANOFORM SUBSTANCES

THANK YOU FOR YOUR ATTENTION

ACKNOWLEDGEMENT

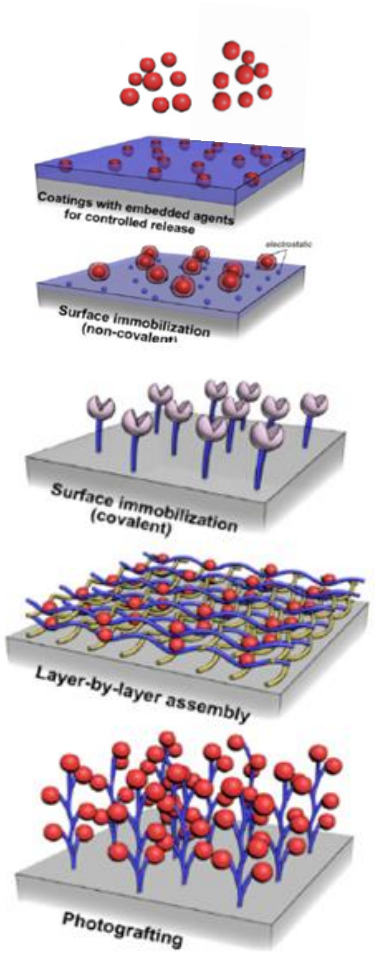
This work is based upon work from COST Action FP1405 ActInPak, supported by COST (European Cooperation in Science and Technology)

COST FP1405

ACTIVE AND INTELLIGENT FIBRE-BASED PACKAGING – INNOVATION AND MARKET INTRODUCTION

COST is supported by
the EU Framework Programme
Horizon 2020

WHICH SUBSTANCES are considered ACTIVE….



WHAT DOES HAPPEN IF THE ACTIVE SUBSTANCE IS ALSO PART OF THE PASSIVE MATERIAL (i.e. plastic)??

The overall migration of a plastic film containing an active substance can exceed the LIMIT of 10 mg/dm^2

The transfer of these active substances should not be included in the calculation of the overall migration limit