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### **INTRODUCTION AND SCOPE**

Active and intelligent packaging represent a real opportunity to extend the shelf-life of many perishable products and fight food waste, going beyond the food protection function. Technologies such as oxygen and ethylene scavenging, humidity regulating, antioxidant, antimicrobial and anti-fungal releasing are typical examples of active packaging. The global demand for active packaging is forecast to further grow in the next decades. Demand will be mainly driven by the food safety and security concerns, together with the mission to reduce food loss and waste along the supply chain.



In the European Union, any food packaging is considered as food contact material and, for this reason, it shall comply with the existing rules related to the consumer's safety. In particular, those materials and articles that are considered active or intelligent must lay down the general European Framework Regulation (EC) 1935/2004, the Regulation 450/2009 (EC) and other national rules, if they exist. All suppliers may place the active packaging solutions on the market if the restrictions set out in the European regulations are complied with. In other words, active packaging solutions shall only be authorized if it is demonstrated they do not present risks to the human health. The interpretation of these laws from a practical point of view is not as easy as one thinks: the safety of active packaging solutions is referred only to those substances that have "active" effects on foods and not on the whole active material or article.

The European Food Safety Authority (EFSA) is in charge of performing a risk assessment on those substances with the final aim to create a "Community list" of authorized substances that can be used in components of active materials and articles, with possible restrictions. The suppliers of active packaging have the responsibility to prepare and submit a Dossier that must be validated by EFSA before the introduction of active substances into the Community list. Although this process has been explained by both EFSA in the Guidelines proposed in 2009 (The EFSA Journal, 2009) and in the EU Guidance by the Health and Consumer Directorate-General in 2011 (EU Guidance, 2011), many questions and uncertainties emerge frequently when a Dossier must be prepared or when an active packaging solution is developed for food contact applications.

The aim of this document is to offer an overview on Active and Intelligent packaging legislation, trying to answer questions related to the risk assessment and authorisation procedure. Migration in general is not part of this focus.

The legal implications for the food contact materials can also offer a contribution to orient the scientific research, in order to better finalize the active solutions and make them effective for the society.

The suggestions presented in this document do not replace the opinion of the Authority and do not provide legal advice on issues of national law.

### THE CURRECT STATUS

#### THE CURRENT STATUS OF ACTIVE MATERIALS AND ARTICLES IN EUROPEAN LEGISLATION

Active food packaging solutions are considered food contact materials, thus they shall only be authorized if it is demonstrated they do not present risks to human health. (art. 8, Reg 1935/2004). Hence, there are several regulations that are relevant for active food packaging:

- Framework Regulation (EC) 1935/2004,
- Regulation (EC) 450/2009,
- Regulation (EC) 2023/2006.

The following paragraphs describe the current status of this European Legislation. However, these might change over time.

#### **ACTIVE VERSUS PASSIVE**

Before going into detail on the different regulations, it is important to understand the difference between the used terminology **active** and **passive**. The definitions listed in this paragraph can help the reader to distinguish what is meant by "active" from a legislative point of view and what is not considered "active" for the safety evaluation under the Regulation 450/2009 (EC). In general, an *active packaging* (AP) is intended as a material or article that *deliberately incorporates components that would release or absorb substances into or from the packaged food or the environment surrounding the food* as expressed in the Regulation (EC) 450/2009.

A first classification of active packaging is based on the form of interaction between the material and the food. Therefore, an active packaging solution can be considered a *releasing* system or an *absorbing/adsorbing* system. The substance that is released into food is considered the *released active substance*.

For example, a typical releasing active material is an antimicrobial film that releases a substance able to reduce the microbial spoilage when put in contact with food. A common absorbing system is a pad used to absorb the drip from meat or fish in a package or a sachet able to remove oxygen from the headspace. The difference between **absorption and adsorption** is instead based on the physic-chemical mechanism that characterizes the material. Thus, the absorption is a bulk phenomenon in which a fluid is dissolved by a liquid or a solid (that is called absorbent). The adsorption is a surface phenomenon in which the molecular species to be removed accumulates at the surface rather than in the bulk.

**Releasing active materials and articles** are those active materials and articles designed to deliberately incorporate components that 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.

Absorbing/adsorbing active materials and articles are those active materials and articles designed to deliberately incorporate components that absorb and/or adsorb substances from the packaged food or the environment surrounding the food.

Whatever the material is absorbing, adsorbing or releasing, it usually consists of specific substances that are directly involved in the active reactions and other substances that indirectly support the action mechanism. For the safety concerns, with the term *active* only individual or combination of individual substances which cause the active function are considered, including the products of in situ reaction of these substances. Therefore, the attention shall be focused on the substance or the combination of substances that explicates a specific function on the food and not on the material and/or the article where these substances are included or contained. The material into which the active substance is added or incorporated is considered a **passive** part of the active solution.

**Passive part** means all materials and articles into which the active component is added or incorporated. **Active substance** and **component** mean individual or combination of individual substances which cause the active function of a material or article, including the products of in situ reaction of these substances.

# THE FRAMEWORK REGULATION OF FOOD CONTACT MATERIALS

The Framework Regulation (EC) 1935/2004 on Food Contact Materials (FCM) establishes that Active and Intelligent materials and articles (hereinafter called A&I) are included in its field of application, thus they must

meet all its provisions to ensure the health and safety of the consumer. This means that active and intelligent materials and articles, as all the other food contact materials, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof (Art.3, Reg. (EC) 1935/2004).

However, this principle can be considered as contradictory for A&I materials and articles that interact directly or indirectly with foods. For this reason, the Framework Regulation provides for special requirements referred to A&I materials and articles (Art. 4, Reg (EC) 1935/2004).

In the application of this Article (at the point b and c), it is well specified that Active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the food legislation. Therefore, the attention passes from the material itself to those components of the material that, changing the composition or the sensorial profile of foods, shall be considered as food additives and/or flavorings and request appropriate authorization in accordance with the relevant EU provisions applicable to food. Relevant provisions laid down under the Reg. EC 1935/2004 are summarized below.

- Active materials and articles shall not bring about changes in the composition or organoleptic characteristics of food, for instance by masking the spoilage of food, which could mislead consumers.
- Active materials and articles already brought into contact with food shall be adequately labeled to allow identification by the consumer of nonedible parts.
- Active materials and articles shall be adequately labeled to indicate that the materials or articles are active.

#### THE SPECIFIC MEASURE FOR A&I MATERIALS AND ARTICLES

The specific measure Reg. (EC) No 450/2009 under the Framework Regulation regulates the active and intelligent materials. This measure, reflecting the principles set up in the Reg. (EC) 1935/2004, includes additional provisions in order to better explain the safety of an AP material or article. In this document, a specific focus has been given to the substances that have a primary role in the active functions, namely those that are directly involved in absorbing or releasing reactions.

The migration of individual substance or the group/combination of substances from A&I materials into food represents the main risk for the consumer. Therefore, an individual substance or the group/combination of substances, which make up the active or intelligent component should be safe and comply with the requirements in the Framework Regulation (EC) No 1935/2004 and the Regulation (EC) No 450/2009. The European Food Safety Authority (EFSA) is in charge of the risk assessment of those substances and the opinion will be considered by the European Commission for the adoption of a Community list of authorized substances, including the combination of substances that, interacting at each other, can lead to an enhancement of the function or the generation of new substances responsible for the active and intelligent function. In this case, EFSA may propose recommendations,

specifications and/or restrictions especially on a substance or a group of substance. At the same time, EFSA may also suggest special conditions of manufacture of materials and articles in which the active substances are incorporated or specific conditions of use in order to reduce the risk for the consumer.

For the safety evaluation by EFSA a specific Dossier shall be submitted using the application guidelines published by EFSA in 2009 (The EFSA Journal, 2009). The relevant information requested by EFSA concern the migration of the active and/or intelligent substance(s), the migration of their degradation and/or reaction products and their toxicological properties.

A schematic overview of the information requested by EFSA in the technical part of the Dossier is shown in a chart on the next page.

On page 9, find a summary of the legislation.

## **TECHNICAL DOSSIER**

OVERVIEW OF APPLICATION	Target function		
	Composition		EC Reg
	Structure	-	EC Reg
	Working principle		
PASSIVE PART	Description		
ACTIVE PART	Identity of the		Regener
	Phisical/chemical	_	
	Manufacturing process	_	
	Toxicological data		Pla
	Existing authorisation		
	Migration data		
	Intended use	Range of food categories	Syn
		Intended and worst case	Activ
		conditions of use	Paj
		for the intended use	

### **LEGISLATION SUMMARY**

	FOR ALL FOOD	
egulation 1935/2004 egulation 2023/2006	It sets out the The GOOD MAN process is well	
	SPECIFIC	
nerated Cellulose Film		
Ceramics		

Regenerated Cellulose Film	
Ceramics	
Plastic Materials	Re Regula
	artic
Synthetic Rubbers	
Active and Intelligent	
Paper and board Glass Cork Stainless Steels-Metals Tissues Adhesives Resins ion exchange Inks and dyes Silicons Coatings Wax	

### OR ALL FOOD CONTACT MATERIALS

general principles of safety and inertness for all FCMs. UFACTURING PRACTICES ensure that the manufacturing controlled so that the specifications for FCMs remain in conformity with the legislation.

#### EU MEASURES

Directive 2007/42/EC

Directive 84/500/EEC I amendment 2005/31/EC

Consolidated version of egulation (EU) No 10/2011 and amendments ation (EU) 2016/1416 – amending and correcting Regulation (EU) No 10/201 for the specifics of these amendments Regulation (EC) No 282/2008 on recycled plastic materials and cles intended to come into contact with foods

Directive 93/11/EEC nitrosammine

EC regulation 450/2009

National Rules

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### THE PRINCIPLE OF INERTNESS

For the most common food contact materials (plastic, paper, glass, etc), **the principle of inertness** is based on the risk evaluation associated to the migration of intentionally or nonintentionally added substances from the packaging materials into food. In fact, substances with a low molecular mass (< 1000 Da) in contact with specific foods or beverages could migrate in particular conditions of temperature and time, therefore consumers may be exposed to potentially harmful chemicals.

In order to guarantee the consumer's healthiness, the safety of the substances used in the formulation of FCM (food contact materials) must be previously verified by the national and European Authorities before their use and, in the final materials, the level of migration of specific substances under the intended conditions of use could be requested on the basis of the existing legislations in Europe and/or in the Member States.

In the debate about safety of A&I packaging, the principle of inertness as FCM on the one hand and then the implicit definition of release and/or absorption of active packaging on the other hand, seems to be a contradiction in terms. In other words, how can the principle of inertness of an active material be implemented considering its attitude to interact actively with the food, releasing or absorbing/adsorbing substances? In fact, due to its deliberate interaction with the food and/or its environment active packaging poses new challenges to the evaluation of its safety as compared to the traditional packaging (Dainelli et al., 2008).



In the *traditional packaging* the migration of substances from packaging into food should be prevented and limited, while in the the *active packaging* the migration of some active substances from packaging into food could be desired and enhanced.

Both the EU Health and Consumer Directorate General and the European Food Safety Authority (EFSA) supported the Member States with specific Guidance documents (2011) that help to understand the safety evaluation of an A&I packaging solution, precisely because it is not an easy subject. From a safety point of view, it is necessary to distinguish an *active substance/* component from the one that is not considered as *active by breaking down* its peculiar components: this practical exercise can help in understanding that an active material or article will rarely consist as a single substance.

More frequently, an AP is composed by a so-called passive part that is a material or an article into which the active component is added or incorporated and by an active part that is an 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. Therefore, the final packaging (a bottle, a sachet, a label, a pad, a film etc.) will be defined active if some of its components exert a measurable and positive effect on the shelf-life extension or on the condition of packaged food. However, only the active part will be the subject of the

specific regulation (EC) 450/2009 and the *active substances* present in the formulation need first to be evaluated by the EFSA before their possible inclusion into a positive Community list.

As declared in the specific Reg. (EC) 450/2009, only individual substance or group/combination of substances which are included in the 'Community list' of authorized substances may be used in components of active and intelligent materials and articles. Concerning this point, it can be useful to exclude those substances that do not need to be listed in the Community list for A&I authorized substances, trying to list them as follows:

 Substances deliberately incorporated into active materials and articles that are *released into* the food or the environment surrounding the food. These substances shall be already approved by food legislation or previously evaluated by EFSA in the context of the Food Law Regulation.
» However, the substances already approved in food legislation must be verified from a safety point of view if chemical reaction, degradation or decomposition is likely to occur under the active packaging manufacturing and processing conditions.

- Substances behind a functional barrier that, by definition, will not migrate in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties.
- » In this case data about the effectiveness of a functional barrier shall be obtained and proposed in the Dossier for the evaluation by EFSA.
- » The functional barrier concept cannot be applied to those substances that are present in nanoform. In this case, a risk assessment based on the case-bycase approach shall be carried out by EFSA.
- All the substances that enter in the formulation of the passive part and are not involved (directly and indirectly) with the active function.
- » In this case, the passive parts of the active packaging materials must also comply with the rules applicable to the same materials and articles when they do not contain the active component, such as the Plastics Regulation (EU) No 10/2011 and its amendments. For materials such as paper and board for which the specific requirements are not regulated at EU level existing national legislation should be applied.

In order to better understand this point, some examples related to common active packaging solutions are described and discussed to offer practical support to possible applicants interested in the safety evaluation of active materials and articles under the Reg. (EC) 450/2009. These examples are presented in the following chapters and are divided into absorber/adsorbent systems and releasing systems.







### **EXAMPLES - ABSORBENT/ADSORBENT SYSTEMS**

#### **GAS ABSORBER IN A SACHET**

For example: oxygen absorber, ethylene absorber, etc.

In this example, a gas absorber sachet made on both side of a laminated film contains a powder that is able to scavenge oxygen from the headspace of packaged foods.The laminated film would prevent the physical release of the powder components into the food and the sachet can be placed in the headspace of the packaging when used in direct contact with foods.

#### **PASSIVE PART**

The film that forms the sachet represents the passive part of the active packaging. Therefore, its safety must be complied with the European and/or national provisions on the basis of the nature of the material itself (i.e. plastic, paper, multilayer multimaterial, ink, adhesive etc.).

#### **ACTIVE COMPONENTS**

The substances included in the powder formulation that are directly involved in the absorbing reaction should be considered as components that cannot be necessarily considered as active. The main active ingredient of the gas absorber is in this case a *single substance* (the real active ingredient) which reacts directly with the gas in presence of other substances (that work, for instance, as carrier), thereby removing the gas itself from the primary packaging. As demonstrated by the information provided by the applicant to EFSA, all the substances constituting the gas absorber (included the active substance) are authorized for use as additives in plastic materials and articles in contact with foods with some restrictions, as food additives or as food supplements in the relative EU Regulations, with or without restrictions.

- Being the active substance yet authorized, no further toxicological data are requested by EFSA for the dossier preparation. The active substance that makes up the oxygen absorber should be evaluated by EFSA on the basis of non-toxicological data and other information provided by the applicant and it should be included in the Union list by Regulation (EC) 450/2009 with possible restrictions.
- Being the other substances used as carrier not involved in the active function, they should comply with

- European or national legislation related to food contact materials. In other words, if the interaction between the active substance and the other substances do not lead to an enhancement of the function, the substances do not need to be inserted in the Community list for the active packaging under the Regulation (EC) 450/2009.
- As the interaction between the active substance and the other substances do not generate new compounds, no toxicological information need to be added to the Dossier.
- EFSA, on the basis of non-toxicological data and other information provided by the applicant (i.e. overall and specific migration data), can verify that no migration of substances from the whole sachet/label etc. occur under the intended conditions of use. EFSA, in its opinion, can suggest the proper conditions of contact with foods, avoiding, for instance, the contact with liquid food or foods that have an external aqueous liquid phase on the surface.

The active ingredient of the gas absorber contained in a sachet is a *mix of substances*. All the substances constituting the gas absorber system are authorized additives in plastic materials and/or authorized food additives or food supplements. However, in this example, the interaction between the gas and the ingredients in the formulation supports and improves the absorption activity generating also new compounds that contribute to the active function.

- The mixture as such has not been evaluated by the EFSA in the past. Therefore all the substances need to undergo the risk assessment and are subject to authorization under the Req. (EC) 450/2009. If the substances are inserted into a list of authorized substances for plastics and/or food additives and supplements, new toxicological information are not needed, being all these substances yet authorized and previously evaluated. Thus the applicant should provide to EFSA all the non-toxicological information as requested by the Guidelines of DG-SANCO (2011) and the mixture as such should be included in the Union list by Regulation (EC) 450/2009 with possible restrictions.
- If new substances are generated from the reaction and they have a direct effect on the absorption reaction, they are subject to authorization to

be included in the Union list of Active and Intelligent substances. Thus, all the information requested by EFSA (toxicological and non-toxicological) are needed.

 EFSA, on the basis of toxicological and non-toxicological data and other information provided by the applicant (i.e. overall and specific migration data), can verify that no migration of substances from the whole sachet/ label etc. occur under the intended conditions of use. EFSA, in its opinion, can suggest the proper conditions of contact with foods, avoiding, for instance, the contact with liquid food or foods that have an external aqueous liquid phase on the surface.

#### GAS ABSORBER INCORPORATED INTO A PLASTIC FILM

In this example, the active formulation is blended with a polyolefin to form a film that incorporates a modified iron based oxygen absorber.

Besides modified iron (named A), the absorber contains, as starting substances of the absorption reaction, two ingredients (a phyllosilicate clay, named B, that contains naturally aluminum, named C) and a compound D generated in the modification process of the natural clay B. All the starting substances B, C and the new generated inorganic compound D have been evaluated and approved for use as additives in plastic food contact materials with some restrictions.

The absorber is intended to be incorporated at a level up to a certain concentration (named X % w/w) in the polyolefin in contact with any type of foods for long term of storage at room temperature or refrigeration.

#### **PASSIVE PART**

In this example, the polyolefin film in which the active substances are incorporated is a plastic layer (i.e. the passive part) and it must be in compliance with the Framework Regulation for FCM and with the Regulation on plastic materials and article.

#### **ACTIVE COMPONENTS**

The substances A-B included in the formulation are directly involved in the absorption function. The substance C is a component of B while D is produced in the modification process of the natural clay and represents a residual substance not directly involved in the absorption process. Thus, the substance D is not an active substance. All the substances A, B, C and D present specific restrictions in the Union lists of additives for Plastics in FCM and of food additives. Substances C (aluminum) and D (a new generated inorganic compound) are characterized by tolerable daily intakes.

- All the toxicological data are well known being the substances yet present in authorized union lists. However, data on migration of iron (A), aluminum (C) from the clay B, and the chemical element D produced in the modification process of the natural clay, is of interest (all these substances present a limitation in the Union list of Plastics and/or are characterized by a tolerable intake level).
- Migration tests should be carried out with a polyolefin film in direct ontact with suitable food simulants (i.e. the acidic simulant in this example) in order to verify if migration of the substances is lower than the SML values and the estimated intakes are observed.
- EFSA should suggest the maximum concentration (% w/w) of the modified iron based oxygen absorber as a

restriction in terms of maximum quantity in the final product when put in contact with specific foods. If no direct contact is expected (i.e. if the modified absorber is separated from the food by a passive material that does not contain the compounds and prevents the physical release into food), EFSA could conclude that the substance does not raise a safety concern.

• After the risk evaluation, the mix of A-B-C should be inserted in the Union list of active substances.

#### **MOISTURE AND LIQUID ABSORBER**

For example: pads, trays, lids that contain mix of substances.

In this example, three different substances (named A-B-C) are used in combination to absorb water from fresh foods. The substances are placed in components in the food packaging preventing them from being in direct contact with food. The concentration of the mixture is equal to a certain X % (w/w) value. After absorption of water a firm gel is formed. The mixture and the gel formed do not come in direct contact with food being separated from it by a permeable fabric. The substance A is an approved food additive and may be added to all foodstuffs following the quantum satis principle; substance B is authorized as additive for plastic materials and articles in contact with foods with specific restriction and substance C is an approved food additive without restrictions.

#### **PASSIVE PART**

The permeable fabric should respect the European Framework Regulation (EU) 1935/2004 and being the specific material do not regulated at European level, possible national provisions should be respected for food contact applications.

#### **ACTIVE COMPONENTS**

- The active substances constituting the absorbent mixture have already been evaluated from the toxicological point of view and they are authorized in the EU legislation as direct food additives and additives for plastics in contact with food. Therefore, no further toxicological data could be necessary in the Dossier.
- The mixture as such has not been evaluated by the Scientific Committee on Food (SCF) or EFSA in the past.

Thus, for the risk assessment evaluation, EFSA can take into consideration possible migration data in the worst foreseeable conditions of use of the substance with restriction (in this example the substance B) and its conservative scenario consumption with existing total weight intake. Some restrictions can be suggested (in terms of maximum concentration in the finale device) for substance B, in order to observe toxicological implications when the substances are placed in components in the food packaging preventing them from being in direct contact with food and the fluid absorption capacity of the absorber is not exceeded.

• After the risk evaluation, the mix of A-B-C should be inserted in the Union list of active substances.

### **EXAMPLES - RELEASING SYSTEMS**

The examples are referred to those active materials and articles designed to deliberately release substances like antimicrobials and antioxidants. Unlike absorbing/adsorbing systems, the release of some substances from packaging into food is highly desired in order to offer a protection and reduce food spoilage during the shelf-life. In the field of food contact materials, special considerations must be done for antimicrobial substances, falling this category under different legal frameworks. EU Guidance to the Commission Regulation (EC) 450/2009 specifies some sub-categories of antimicrobials and their legislative reference. See the table below.

SUB-CATEGORY	FUNCTION	WHERE THEY ACT	RELEASE INTO FOOD	LEGISLATIVE REFERENCE
Surface antimicrobials	Keep the surface of the food contact material free from microbial contamination	Surface of the FCM	NO	Biocide Products Regulation (EU) 528/2012
Process antimicrobials	Keep the components (ingredients, preparations etc) free from microbial contamination during production, storage, handling of FCM	In the components used for the manufacture of FCM	NO The substance should not be present also in the final FCM.	Specific measures on FCM (e.g. Regulation EU 10/2010 and amendments on Plastics)
Preservatives	Prolong the shelf-life of foods from spoilage microorganisms. Protect the safety of foods from pathogenic microorganisms.	On/into the food (surface, bulk)	YES	Commission Regulation EC 1333/2008 and implementing/amending measures (EU Regulations 234/2011, 1129/2011 and 1130/2011)

On the basis of this classification and the legislation in force, only a preservative intentionally incorporated into a FCM that is intended to be released into food is considered as an active substance. In this specific case, it has a technological effect on foods during/ after its release. However, since the released substance will be eaten by the consumer, it will fall under the existing food law. This means that all the substances incorporated into FCM

that act as preservative when released into food can be used in accordance with EU and national provisions applicable to food and the provisions of Regulation (EC) No 1935/2004. For those substances, the authorization procedure under the Reg (EC) 450/2009 shall not be required. If the released substance is not yet authorized by EU and national provisions, an evaluation and authorization procedure shall be ask under the EU provisions on food additives. For this reason, this kind of substances will not be included in the Union List of active and intelligent materials and articles. However, the stability of these substances under the packaging manufacturing and processing conditions must be verified by the manufacturer and a dossier for safety evaluation has to be submitted if it demonstrated that chemical reaction, degradation or decomposition of the substances can occur.

#### ESSENTIAL OILS USED AS ANTIMICROBIAL AND ANTIOXIDANT

In this example, two different essential oils are coated onto a plastic material in order to release their constituents, acting both as antimicrobial able to reduce microbial food spoilage and as antioxidant reducing surface oxidations. Thus, in this application, essential oils act as preservative for the packaged food.

- In the current European food regulation this specific use of essential oils is not authorized.
- According to Reg EU 450/2009, released active substances shall be used in compliance with the relevant community and national provisions applicable to foods. An evaluation and authorization procedure shall be submitted in the context of the European regulation on food additives
- Being used as preservatives, the active substance will not be included in the Union list of active and intelligent FCM

#### ORGANIC SUBSTANCES INCORPORATED IN A PLASTIC POLYMER...

...by means of a grafting technique and used as preservative in food

In this example, the grafting technique has been used to modulate the release of the active substance into food. The release of the organic compounds grafted on the polymer act as food additives and has a technological function in the food. For this reason, the substances involved in the active mechanism are covered by the legislation on food additives and enzymes and are therefore treated in the same way as released active substances.

- If the organic substances are listed in the EU list for food additives and flavoring, the risk assessment and the authorization are not requested under the Reg EC 450/2009
- If the organic substances are not authorized, application should be submitted for risk assessment and authorization as preservative under the Commission Regulation (EU) No 234/2011 for establishing a common authorisation procedure for food additives, food enzymes and food flavourings
- Being used as preservatives, the active substance will not be included in the Union list of active and intelligent FCM
- The passive parts of the solution lay down the legal aspects for plastics as FCM.

### **LEGISLATION LEAFLETS**

A series of short-text leaflets on the topic of legislation for active and intelligent packaging has been published.

On the right, there are clickable links to web versions of the ActInPak's Legislation leaflets in various languages named after their country of origin.

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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 Web: https://eur-lex.europa. eu/legal-content/en/ ALL/?uri=CELEX%3A32004R1935

Commission regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food Web: http://eur-lex.europa. eu/legal-content/EN/ ALL/?uri=CELEX%3A32009R0450

The EFSA Journal (2009). 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. 1208, 3-11. Web: https://www.efsa.europa.eu/en/

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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. European Commission. Health and Consumers Directorate-General

Web: https://ec.europa.eu/food/sites/ food/files/safety/docs/cs\_fcm\_legis\_ active-intelligent\_guidance.pdf

EFSA community list: Web: https://webgate. ec.europa.eu/foods\_system/ main/?sector=FCM&auth=SANCAS

Dainelli et al., 2008. Active and intelligent food packaging: legal aspects and safety concerns. Trends in Food Science & Technology. 19, S103-S112. Web: https://www.sciencedirect. com/science/article/abs/pii/ S0924224408002355

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countries have already legislated against countries name legislate to change of time... You cannot legislate to change of the legislate a national energy of the legislate of the legisl pproval time... Tou control of the second sec legis la tion /led 31slei sn/ legis of a law or laws passed by a story of a letter calling for logic COUNT: [FORMAL] ...a letter calling for legislati te N of women sugar ledgislative /ledgislativ, AM -leileg is involving or relating to the tive means involving laws. [FORMALL tive means and passing laws. [FORMAL] Q 7 making and the first step in the legislative hod ...the country's highest legislative body. legislator /ledgisleitar/ (legislate islator is a person who is involved in passing laws. [FORMAL] ... an attempt to Islators to legislature /led3islatfar, AM -lei-/ tures) The legislature of a particular country is the group of people in it who

COST FP1405 ActInPak aims to identify and overcome the key technical, social, economic and legislative barriers to a successful deployment of renewable fibrebased functional packaging solutions such as active and intelligent packaging. Currently, 43 countries are involved in the network, with participants representing 209 academic institutions, 35 technical centers, and 83 industrial partners.

For more information, please visit the ActInPak website:

#### www.actinpak.eu

COST (European Cooperation in Science and Technology) is a funding agency for research and innovation networks. Our Actions help connect research initiatives across Europe and enable scientists to grow their ideas by sharing them with their peers. This boosts their research, career and innovation.

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