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

This guidance was presented to the Member States in the Standing Committee section Toxicological Safety on the Food Chain of 23 November 2011 for information.

The guidance is aimed at European Professional Organisations and Member States competent authorities dealing with questions concerning the interpretation and implementation of certain aspects in this legislation. This document is an evolving document and will be updated to further clarify aspects related to the implementation of this legislation.

This document is made available on the DG Sanco website on food contact materials: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

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TABLE OF CONTENTS

1 Scope: definitions and examples

This part lists the legal definitions related to active and intelligent materials and articles as given in Article 3 of Regulation (EC) No 450/2009. It gives an interpretation of the definitions by means of examples. Also examples of packaging not falling within the scope are given.

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.

- '**component'** means an individual substance or a combination of individual substances which cause the active and/or intelligent function of a material or article, including the products of an in situ reaction of those substances; it does not include the passive parts[1] such as the material they are added to or incorporated into;

The component might be the individual active substance only. The component can also be a combination or group of substances that e.g. when the active or intelligent function implies interaction between different substances leading to an enhancement of the function or the generation of new substances responsible for the active and intelligent function.

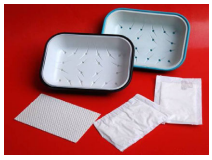
Active packaging is a type of food packaging with an extra function, in addition to that of providing a protective barrier against external influence. Active packaging is intended to influence the packed food. The packaging absorbs food-related chemicals from the food or the environment within the packaging surrounding the food; or it releases substances into the food or the environment surrounding the food such as preservatives, antioxidants, flavourings, etc.

1.1.2 Examples of active materials and articles

Following the definition of active materials and articles, we can group the examples as follows:

A) Absorbing/scavenging systems:

- Moisture absorbers:
  Pads used for example to absorb the drip from meat, poultry and fish in display packs. They may for example consist of a laminate of plastic gauze, adhesive and pads containing polymeric fibres or granular polyacrylates only or in combination with natural cellulose all contributing to the absorbing function of the pad.
  Materials and articles functioning on the basis of the natural constituents only, such as pads composed of 100% cellulose, do not fall under the definition of active materials and articles because they are not designed to **deliberately incorporate components** that would release or absorb substances. Further examples on absorbers that fall and do not fall under the definition of active materials and articles are given in part 1.4.



[1] Part 2.2.4 explains the legal aspects related to the passive parts of packaging

- Scavengers:

    - 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.

    - Ethylene scavengers may be used in sachets or incorporated into a polymer film. An example of an application is a plastic fruit bag with an ethylene scavenger incorporated. Ethylene, a natural plant growth hormone, is a key to the ripening process of fruits and vegetables, being liberated during respiration and then driving the ripening process itself. The active component is meant to prevent an excess of the gas in order to extend shelf life of the packaged product.

B) Releasing systems:

- **Applications are packaging that contain releasing substances** such as preservatives, antioxidants, flavourings, enzymes. These released active substances are intentionally added into or onto the packaged food to fulfill a purpose in the food or the environment surrounding the food and to maintain or extent the shelf-life of the packed food.

C) Systems with substances grafted or immobilized on wall of the packaging:

- **Applications are packaging containing a substance such as an additive or enzyme which is grafted on the surface in contact with food and has a technological effect on the food.** These materials incorporate (an) active component(s) that deliberately influence the condition of the food without intentional migration. This category of packaging is thus similar to the previous (B) with the difference that the active substance is not released into the food but it stays grafted or "immobilized" on the surface of the packaging where it performs its function; any migration into food is non-intentional.

Anti-microbial packaging – effect by contact

1.2 Intelligent materials and articles

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.

1.2.2 Examples of intelligent materials and articles

A packaging with a time-temperature indicator is an example of an intelligent packaging. Time-temperature indicators are meant to give information on whether a threshold temperature has been exceeded over time and/or to estimate the minimum amount of time a product has spent above the threshold temperature (time temperature history) e.g. from the moment the food it is packed until consumption. The indication is often a visual signal. A positive visual signal could indicate that a product is not fresh anymore or not suitable to be eaten. The information provided shall be reliable and correct and should not mislead the consumer. Further information is also given in part 2.2.7.

1.3 Functional Barrier

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

- **'Functional barrier'** means a barrier consisting of one or more layers of food contact materials, that ensures that the finished material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with this Regulation.

This barrier is a layer within the food contact materials or articles preventing the migration of substances from behind that barrier into the food. The maximum tolerated migration level is 0,01 mg substance /kg food for a substance. This migration limit is applicable to a group of substances if they are structurally and toxicologically related, in particular isomers or substances with the same relevant functional group; it also includes possible set-off transfer. This limit shall always be expressed as a concentration in foods. If it is demonstrated that the packaging material or a layer acts as a functional barrier to migration then non-authorised substances can be used in the layer(s) behind the barrier (not on the food contact side) provided they don't fall under one of the following categories:

- Substances that are *mutagenic, carcinogenic or toxic to reproduction* should not be used in food contact materials or articles without previous authorisation and are therefore not covered by the functional barrier concept.
- 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.

This should be demonstrated in the declaration of compliance and the supporting documentation [(EC) No 450/2009 Article 13 and Annex II (10)].

1.4 Clarifications on types of packaging or components that fall or do not fall under the definition of active and intelligent materials and articles

To clarify whether certain types of packaging fall or do not fall under the definition of active or intelligent materials and articles, the following examples are described. Obviously it is not possible to describe all possible examples. To materials and articles that do not fall under the definition, other EU legislation on food contact materials applies. To materials and articles for which no specific requirements at EU level exist, national legislation applies. Part 4.19 provides further information.

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.

Types of packaging or components that fall under the definition	Types of packaging or components that do NOT fall under the definition
	Pads composed of natural cellulose and polymeric fibres or only polymeric fibres that do not contribute to the absorbing function Absorber pads made of cellulose fibres and polymeric fibres or only polymeric fibres that do not contribute to the active absorbing function, are not considered as active components. The fibres are used to form tissues, fluffs or non-woven fabrics. The effect is created by the structure of the materials formed by the fibres: they include cavities that take up moisture released from foods. The take-up of moisture is not caused by intentionally added substances. Such pads can be regarded as paper or materials composed of paper and plastic.
Absorbers, that exert their effect on packaging gases (e.g. modified atmosphere packaging) or on other substances that may be generated by the packaging material and have come into the environment surrounding the food, are covered by the definition. The absorption of those substances is meant to help to maintain the condition of the packaged food. Very often, such absorbers absorb volatile substances.	**Absorbers that exert their effect on substances that constitute the packaging material** and not on the food or the environment surrounding the food are not covered by the definition. Such absorbers may have the aim to suppress the release of those substances from the packaging into the food or the environment surrounding the food. Example of the above may be an absorber of acetic acid that may be generated from the extrusion of EVA polymers, or an absorber of acetaldehyde from PET.

Types of packaging that fall under the definition	Types of packaging that do NOT fall under the definition
Releasing Systems	
	Wooden barrels Wooden barrels are very widely used for the storage and maturation of whisky, wine and other alcoholic drinks and this has been practice for a very long time. This packaging application has both releasing and adsorbing character, to change and improve the organoleptic qualities of the stored drink. Active food contact materials and articles should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food during the process of their manufacture, such as wooden barrels. Wooden barrels are not designed to **deliberately incorporate** components that would release substances into the food. Therefore, this type of material or article is not considered as active. **Wood chips or flakes** Wooden chips or flakes used for aging of wines, which might have been toasted to match the toasting of the barrel, are not considered as active materials and articles. Since the substances that are released into the food are not intentionally incorporated into the wooden chips, this type of application is not considered as an active material or article.

Types of packaging that fall under the definition	Types of packaging that do NOT fall under the definition
Releasing Systems	
Anti-microbials: General information on the different categories The purpose of use of anti-microbials in food contact materials defines whether the anti-microbial is considered as an active substance or not. Depending on their function in food contact materials, we distinguish the following categories: (1) **Process anti-microbials** keep the material or preparations to be processed into final food contact materials (e.g. pre-polymer solutions) free from microbial contamination during the production, storage or handling process; ➔ They are used as components in the manufacture of food contact materials but not intended to be present in the food contact material itself ➔ As no antimicrobial function is exerted on the final food contact material, the food contact material could not be regarded as treated article. (2) **Surface anti-microbials** keep the surface of the food contact material[2] free from microbial contamination (e.g. used on inner surface of fridges, cutting boards, gaskets, conveyer belts, storage containers). However, the anti-microbials are not intended to be transferred to food or its environment and it does not have any technological effect on the food. (3) **Preservatives[3]** have a technological effect on the food. They are defined as substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms. Their function is to prolong self-life by protecting food against 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.

[2] At the moment, a proposal on biocides at the Council and Parliament which, if adopted, would foresee that if such substances are used as surface anti-microbials or biocides in food contact materials, these food contact materials would be considered as "treated articles". However, if a food preservative, which is not covered by the biocide regulation, is incorporated to be released from a material or article this material or article would not be considered as a treated article. Only surface anti-microbials would fall under the scope of the commission proposal on Biocides.

[3] Preservatives are explicitly listed in Directive 95/2EC (parts A (B) and C of Annex III). These Annexes of the Directive 95/2/EC apply till June 2013. From then on Annexes II and III to Regulation 1333/2008 apply, as amended by Commission Regulation (EU) No 1129/2011 and (EU) No 1130/2011 resp amending Annex II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients. Preservatives (new food additives or a request for an extension of use) are subject to an authorisation procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, according to the implementing measures foreseen under Regulation (EU) No 234/2011.

Types of packaging that fall under the definition	Types of packaging that do NOT fall under the definition
Releasing Systems	
Extracts having an anti-microbial or preservative effect on the food or any other technological function Extracts from plants, micro-organisms or animal origin can be incorporated into the food packaging to exert a function in the food and are covered by the food additives legislation. These extracts are considered as released active substances. Examples of possible active substances: - extract of rosemary as active substance to exert the function as anti-oxidant in the food - nisine (E234 /235), produced by fermentation using the bacterium *Lactococcus lactis*, functioning as preservative The extracts have to comply with the existing legislation on food additives[4], enzymes[5] and flavourings[6]. In cases where an authorisation before its use is mandatory by that legislation, authorisation[7] needs to be sought under that legislation.	

[4] Commission Regulation (EC) No 1333/2008 of the European Parliament and Council of 16 December 2008 on food additives; Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives; Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients.

[5] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

[6] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC.

[7] Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

Types of packaging that fall under the definition	Types of packaging that do NOT fall under the definition
Other Systems	
	Heat-releasers and self-venting packaging Types of packaging with physical effects such as self-venting or self-heating effects are not covered by the definitions of active and intelligent materials and articles. Self-heating packaging is packaging with the ability to heat food contents without external heat sources or power. An example is a self-heating can. Self-heating cans have dual chambers, one surrounding the other. The inner chamber holds the food or drink, and the outer chamber houses chemicals that undergo an exothermic reaction when combined. Other self-heating applications are for example tea, coffee and hot meals. Self-venting packaging is packaging that controls the steam or pressure in the pack, venting the steam when the required pressure temperature level is reached. Applications are for example microware popcorn and microware meals. These physical effects are not covered by the definition of active and intelligent materials and articles.

2 Legal aspects in relation to the authorisation of active or intelligent substances or components

The purpose of this part is to explain the relevant legal aspects as regards the authorisation of active or intelligent substances or components.

2.1 Overview

The Framework Regulation (EC) 1935/2004[8] allows the introduction of active and intelligent packaging on the European market. This Regulation states that food contact materials shall not transfer constituents to food in quantities, which could endanger human health, bring about an unacceptable change in the composition and bring about deterioration in organoleptic characteristics thereof (Article 3).

The Regulation provides specific requirements for active and intelligent materials and articles (Article 4) and includes the following provisions:

- 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.
- Substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food shall be authorised and used in accordance with the relevant EU provisions applicable to food.
- 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.
- Intelligent materials and articles shall not give information about the condition of the food which could mislead consumers.
- Active and intelligent materials and articles already brought into contact with food shall be adequately labeled to allow identification by the consumer of non-edible parts.
- Active and intelligent materials and articles shall be adequately labeled to indicate that the materials or articles are active and/or intelligent.

Commission Regulation (EC) No 450/2009 is the specific measure under the Framework Regulation that regulates active and intelligent materials and articles. This Regulation includes additional provisions:

- The individual substance or 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.
- Substances should undergo a safety assessment by EFSA before they are authorised for use.
- A Union list of substances or group/combination of substances to be used in active and intelligent components should be drawn up following risk assessment of these substances by EFSA.
- Substances released from active releasing materials should comply with any restrictions in the existing food law (e.g. as authorised food additives) thus complying with the safety requirement.
- The overall migration from active releasing materials can exceed the overall migration limits described in EU or national legislation as long as the levels transferred to the food comply with restrictions in the existing food law (e.g. as authorised food additives). The transfer of these active substance/substances should not be included in the calculation of the overall migration limit (OML).
- As well as complying with the Framework Regulation the passive parts of the active and intelligent 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. For materials such as paper and board for which the specific requirements are not regulated at EU level existing national legislation should be applied. The existing national legislation is summarized in document: EU and national laws.
- Intelligent systems that are on the non-food contact surface of the package can be separated from the foodstuff by a functional barrier, i.e. a barrier to any migration. If it is demonstrated that the packaging material acts as a functional barrier to migration then non-authorised substances can be used providing they meet specific criteria defined in the Regulation.

Declaration of compliance

Article 16 of the Framework Regulation (EC) No 1935/2004 provides that materials and articles are to be accompanied by a written declaration of compliance attesting that they comply with the rules applicable to them. Active and intelligent materials and articles, whether or not they are in contact with food, or the components intended

[8] OJ L 338, 13.11.2004, p. 4–17

for the manufacturing of those materials and articles or the substances intended for the manufacturing of those components shall be accompanied by a written declaration at the marketing stages other than at the point of sale to the final consumer. Annex II of Commission Regulation (EC) No 450/2009 contains the required information. When the material or article also has to meet the requirements of other food contact materials legislation, for example under (EU) No 10/2011, then the declaration of compliance also has to contain that necessary information as required by that legislation.

Labeling requirements
Articles 4(d) and 11 of (EC) No 450/2009 specify that active and intelligent materials should be labeled. For example, to avoid that the content of sachets are perceived as edible, these should be labeled as **non-edible**.

Articles 12 and 13 specify that **information should be provided throughout the packaging chain** as well as to the consumer to ensure the correct use of these materials and articles. Active materials and articles which are not yet in contact with food when placed on the market, e.g. a packaging containing an anti-oxidant to be released in the food, are to be accompanied by information on the permitted use or uses and other relevant information such as the name and maximum quantity of the anti-oxidant released by the active component. In this way the food business operators who use these materials and articles are enabled to comply with any other EU or national provisions applicable to food such as the permitted level of the anti-oxidant in the food.

The **labeling of food packed in active materials and articles** that contain substances to be released into the food shall be performed according to the relevant EU labeling provisions. Released active substances are considered as ingredients within the meaning of Article 6 (4) (a) of Directive 2000/13/EC. Food additives remain subject to the general labeling obligations as provided for in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs.

2.2 Examples to explain the legal aspects in relation to the authorisation of active or intelligent substances or components

The legal aspects in relation to the authorisation of active or intelligent substances or components are explained by means of examples.

2.2.1 Active Packaging A: Releasing system

Packaging A is a releasing active packaging. The active component is incorporated in a plastic layer. The active component is composed of several substances of which one is an anti-oxidant that is released from the plastic layer in the packaging into the food to extent the shelf-life of the food.

The released active substance that performs a technological function on the food, the antioxidant, should be authorized to be used as a food additive in the EU and the use should comply with the applicable restrictions and conditions. If the antioxidant is not yet authorized, authorization under the legislation applicable to food additives needs to be requested[9]. The released antioxidant will not be included in the Union list of active and intelligent materials and articles as it will be included in the Union list of food additives.

The other substances that constitute the component e.g. when the active function implies interaction between different substances leading to an enhancement of the anti-oxidant function or the generation of new substances responsible for the anti-oxidant function are also considered as "active substances". These substances are also subject to authorisation under (EC) No 450/2009. They also need to undergo the risk assessment to be included in the Union list of active and intelligent substances. Once the Union list includes those substances, they can be used under the restrictions and conditions specified in the list.

As the active substance is not part of the passive material, the amount of released active substance should not be calculated in the value of the OML.
This OML is a measure for the inertness of a material (the material of the passive part) and is laid down by the Commission Regulation (EU) No 10/2011 on plastic materials and articles. The overall migration from active releasing materials can exceed the overall migration limits described in EU or national legislation as long as the levels transferred to the food comply with restrictions in the existing food law (e.g. as authorised food additives). The

[9] Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

transfer of these active substance/substances should not be included in the calculation of the overall migration limit (OML).
For example, a plastic packaging of frying oil deliberately incorporates the additive E310 (propyl gallate) and is designed to release E310 in amounts of 100 mg per l oil with the aim to have a technological effect (e.g. anti-oxidation) on the oil.
The overall migration limit (OML) applicable to this plastic packaging is 10 mg/dm² [10]. The released amount of E310 should not be included in the calculation of the overall migration limit (OML) and may thus lead to exceeding the OML of 10 mg/dm² set out for plastics as long as the amount of this additive, individually or in combination with other additives E310 – E320, does not exceed 200 mg/l oil[11].

In part 2.2.4 the passive parts and the legal aspects applicable to them are explained.

2.2.2 Active Packaging B: (an) active substance(s) incorporated by grafting or immobilisation

Packaging B is an active packaging containing a preservative incorporated by means of techniques such as grafting or immobilization in order to have a preservative effect on the food.

The same principle applies as for Packaging A. The preservative should only be used under the conditions set out in the relevant EU or national provisions for their use in food. For preservatives the Commission Regulation (EC) No 1333/2008 on food additives is applicable. If not authorised, an application should be submitted for risk assessment and authorisation as preservative under the Commission Regulation (EU) No 234/2011[6].
The active substance(s) such as preservatives will not be included in the Union list of active and intelligent materials and articles as it falls under the relevant EU or national provisions for their use in food.

Food additives or enzymes which are grafted or immobilised on the material and have a technological function on the food are covered by the legislation on food additives and enzymes and are therefore treated in the same way as released active substances.

In part 2.2.4 the passive parts and the legal aspects applicable to them are explained.

2.2.3 Active Packaging C: Oxygen Absorber

Packaging C contains an oxygen absorber which is included, together with other substances, in a separate container, a small sachet.

The active substance(s) that make up the oxygen absorber should be authorized to be used in active materials and articles by Regulation (EC) No 450/2009 and be included in the Union list. Once the Union list has been established and the active substance is authorised, the oxygen absorber can be used in active materials and articles under the conditions specified in the Union list.

Other substances that constitute the component e.g. when the oxygen absorbing function implies interaction between different substances leading to an enhancement of the function or the generation of new substances responsible for the absorber function are also considered as "active substances" and need to undergo the risk assessment and are subject to authorisation to be included in the Union list. The other substances in the sachet, that do not play a role in the active function, belong to the passive part of the packaging. These substances don't need to be authorised under (EC) No 450/2009, but other EU or national legislation related to food contact materials is applicable (e.g. paper, printing inks, etc) to them. In part 2.2.4 the passive parts and the legal aspects applicable to them are explained.

[10] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
[11] Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives

2.2.4 Packaging A, B and C: legal aspects to the passive parts of the packaging

The substances in the active component which do not contribute to the active function (e.g. carrier substances, ….), the layer into which the component is incorporated, the container (sachet), and the other layers of the packaging are considered as the passive part. The passive part should comply with the specific EU and national provisions to those materials and articles. For example,

- Other substances that are part of the active component but do not contribute to the active function should comply with EU or national legislation related to food contact materials. If those are plastic substances, these need to be authorised under the Commission Regulation (EU) No 10/2011. To others, national provisions may be applicable.
- If the layer in which the active substance(s) is/are incorporated is a plastic layer, the plastic layer must be in compliance with the Commission Regulation (EU) No 10/2011 on plastic materials and articles.
- Also the other layers have to comply with the EU or national rules applicable to those materials and articles. For materials such as paper and board that are not yet regulated at EU level, national legislation is applicable.

The website on food contact materials section Document
(http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm) contains the following documents
- An overview of the status of harmonization of EU legislation on food contact materials (FCM)
- A summary of European and National FCM legislation

2.2.5 Intelligent packaging D: a time-temperature indicator behind a functional barrier

Packaging D is an intelligent packaging, a plastic box 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.

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

- 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. In part 1.3. the functional barrier concept is explained in detail.
- The declaration of compliance then has to indicate that the functional barrier concept is applied. In the support of the declaration of compliance appropriate documentation shall be made available to the competent authorities on demand to demonstrate it.

If there is migration above 0,01mg/kg, the functional barrier concept does not apply and authorisation for the substances under Regulation (EC) No 450/2009 needs to be requested.

The passive part of the packaging should comply with the existing EU and national legislations on food contact materials (part 2.2.4).

2.2.6 Intelligent packaging E: a time-temperature indicator incorporated in the food contact surface of the packaging

In contrary to active components, intelligent components are not intended to release their constituents into the food. If the intelligent component is not positioned on the outer surface of the package and/or is not separated from the food by a functional barrier (see Part 1.3.), an application for risk assessment and authorisation under (EU) No 450/2009 should be submitted to be included in the Union list. Once the Union list has been established and the intelligent substance(s) is/are authorised, they can be used in intelligent materials and articles under the conditions specified in the Union list.

The passive part of the packaging should comply with the existing EU and national legislations on food contact materials (part 2.2.4).

2.2.7 Active or intelligent materials and articles with a potential to mislead the consumer on the condition of the food are illegal

Active and intelligent materials and articles should not change the composition or the organoleptic properties of food or give information on the condition of the food that could mislead the consumer. For example, active materials and articles should not release or absorb substances such as aldehydes or amines in order to mask spoilage of the food. Such changes which could manipulate signs of spoilage could mislead the consumer and are therefore not allowed.
Similarly active materials and articles which produce colour changes to the food that give the wrong information concerning the condition of the food could mislead the consumer and are therefore not allowed.

Intelligent materials and articles shall not give information on the condition of food, which could mislead the consumer in the sense that the given information misleads the consumer on the potential spoilage of the food.

2.2.8 Active or intelligent materials and articles should be suitability and effective

How is it assured that active or intelligent materials and articles are suitable and effective? First, the business operator has to declare by means of a written declaration of compliance that his active or intelligent materials and articles, in contact or intended to come into contact with food, are suitable for their intended use and effective. Secondly, the supporting documents should prove the suitability and effectiveness of the active or intelligent material or article, the conditions and results of testing or calculations or other analysis, and evidence on the safety or the reasoning demonstrating compliance. We refer to Article 16 of (EC) No 1935/2004 and Article 12 and 13 of (EC) No 450/2009). The business operator shall make this information available to the national competent authorities on request.

3 Union list of substances that may be used in active or intelligent components

The substances or groups of substances included in the Union list can be used in active or intelligent components under the conditions specified in the Union list. The Union list includes combinations of substances when the active or intelligent function implies interaction between different substances leading to an enhancement of the function or the generation of new substances responsible for the active and intelligent function.

The individual substance or combination of substances that make up the active or intelligent component should first be risk assessed to guarantee that they are safe and comply with the requirements in the Framework Regulation. After the risk assessment a risk management decision is taken for the inclusion in the Union list.

The following substances are **not** included in the Union list	But can be used
1. Released active substances	1. in accordance with EU and national provisions applicable to food, the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures
2. Substances within the scope of EU and national food law added to or incorporated into active materials and articles by techniques such as grafting or immobilisation in order to have a technological effect in the food	2. in accordance with EU and national provisions applicable to food, the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures
3. Substances used in components which are not in direct contact with food or the environment surrounding the food and are separated from the food by a functional barrier (see also Part 1.3.)	3. if they do not migrate above 0,01 mg/kg and are not carcinogenic, mutagenic or toxic to reproduction or are nano particles*

For the active substances in 1. and 2. in the above table, no authorisation scheme is foreseen in the context of active and intelligent materials and articles. These substances can be used in active materials and articles without being included in the Union list and on the condition that their use complies with EU and national provisions applicable to food, the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures. In this way a duplication of authorisation is avoided.

Substances that are mutagenic, carcinogenic or toxic to reproduction and *substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale can only be used after authorisation and when listed in the Union list.

<u>The Union list will include:</u>

- the identity : name, synonym name, CAS No, EC No, particle size*, composition, other specifications
- the function
- the reference number
- the conditions of use of the substance or the component
- the restrictions and/or specifications of the use of the substance
- the conditions of use of the material and article to which the substance or component is added or into which it is incorporated

* The particle size will be included when relevant for the functioning of the system and in the case of substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale (substances in nanoform).

Establishment of the first Union list – The initial authorisation phase

- For inclusion into the first Union list, applications should have been submitted **before 15 February 2011** for the safety assessment. Applications should have been submitted to the national contact points[12] who forward them then to EFSA.
- The Commission shall make available to the public a **register** on the SANCO website which contains all substances for which a **valid application** has been submitted. This register will be available on the DG Sanco food contact materials website Section Documents: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm)
- The Union list shall be adopted by the Commission after the EFSA has delivered its opinion on **all substances included in the register** for which a valid application has been submitted. For adoption of the Union list no deadline is established in the legislation.

Addition of new substances to the Union list

For addition of new substances to the Union list, Articles 9, 10 and 11 of Regulation (EC) No 1935/2004 apply.

[12] The national contact points for applications related to food contact materials is available on the following website: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

4 Questions and answers related to the risk assessment and authorisation procedure

4.1 How do I apply for an authorisation of substances to be used in active or intelligent components?

1. You should draw up an application following the EFSA guidelines[1] and send it to the relevant national contact point[13]. You should clearly indicate that this is an application for use of a substance / group of substances in active or intelligent materials and articles.

2. The national contact point will then send your application to the EFSA for assessment.

3. The EFSA will:
   a) Check whether the application is valid or not and will inform the applicant on this (for further information please see question 4.7.).
   b) If the application is considered to be valid, the EFSA will carry out a risk assessment of the substance or group of substances to see whether it complies with the conditions laid down in Article 6 of (EC) No 450/2009 referring to Articles 3 and 4 of The Regulation (EC) No 1935/2004. The EFSA must give an opinion on this within six months of receiving your valid application.

4. Taking into account the opinion from EFSA, relevant provisions of EU law and other legitimate factors relevant to the matter under consideration, the Commission will adopt a measure to establish and once established to amend the Union list of substances that may be used in active and intelligent components.

To know when an application is necessary, please also read question 4.3. and 4.4.

4.2 What is the role of national contact points?

The national contact points' job is to receive applications from applicants. They must acknowledge receipt of each application within 14 days and must send all the information submitted to the EFSA.

The national contact point (NCP) might verify the scope of the application and indicate it in the mandate to EFSA. The date of reception of the application (received before or after the deadline of 14 February 2011) shall be indicated. In the case that an application was wrongly submitted to EFSA for one of the cases described in question 4.4, EFSA may consider the application as invalid.

4.3 When is an application necessary?

During the initial authorisation phase (question 4.8) to establish the Union list of active and intelligent substances, it is necessary to submit an application for authorisation of substances in active and intelligent components that fall within the scope of the Union list (see also part 3). Cases that do not fall within the scope of the Union list are described in the question 4.4.

As from the date of application of the Union list, only active and intelligent materials and articles including the substances in the list may be marketed, complying with the restrictions and specified conditions of use. For new active or intelligent substances, not yet included in the Union list, a new application should be submitted. The paragraph above remains applicable: submission of applications is not necessary for the cases described in the question 4.4.

[13] http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

4.4 Is it necessary to submit an application for authorisation for each substance to be used in active or intelligent materials or articles? For which substances is it not necessary?

No, it is not necessary to submit an application for authorisation for each substance to be used in active or intelligent materials or articles. Whether or not prior EU authorisation for use in active and intelligent materials and articles is necessary, depends on the type, the function and the composition of the active or intelligent component and the way it is incorporated in the packaging. Also EFSA published guidance concerning the preparation and submission of the application for risk assessment of substances[14].

Authorisation under Regulation (EC) No 450/2009 is not necessary if

1. it is an active releasing material or article. The released active substance can be used in accordance with EU and national provisions applicable to food, the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures. An example is explained in the part 2.2.1.
2. it is an active material or article to which substances are added to or incorporated into by techniques such as grafting or immobilisation in order to have a technological effect on the food. These substances can be used in accordance with EU and national provisions applicable to food, the provisions of Regulation (EC) No 1935/2004 and, when applicable, its implementing measures. An example is explained in the part 2.2.2.
3. if it is an active or intelligent material or article of which the component is not in direct contact with food or the environment surrounding the food and is separated from the food by a functional barrier (see also Part 1.3. and 3). Non authorised substances should not migrate above 0,01 mg/kg and the substances should not be carcinogenic, mutagenic or toxic to reproduction or be nano*-particles (*substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale) An example is explained in the part 2.2.5. and 2.2.6.

Once the Union list has been established, a request for authorisation of the active or intelligent substance(s) in the list is not necessary for their use according to the restrictions and conditions specified in the list.

4.5 The active component of an active releasing material or article is composed of one non-authorised substance that has a technical effect on the food such as an additive. Can I submit an application under Regulation (EC) No 450/2009?

No. The non-authorised substance should be authorised under the respective EU food legislation. For example, in the case of an additive, an application shall be submitted under Commission Regulation (EU) No 234/2011.

If the active releasing component is only composed of that additive and no other substances that interact to enhance the function, no application for authorisation under Regulation (EC) No 450/2009 needs to be submitted. As soon as that additive is authorised to be used in food, it can be used in an active material releasing the additive into the food or into the environment surrounding the food. The parts 2.2. and 3 explain this further.

4.6 Should I submit an application for a substance / a component / the whole active or intelligent material or article?

When a single substance is responsible for the active or intelligent function then an application for a substance should be submitted.
When the combination of substances which constitute the active or intelligent component, e.g. when the active or intelligent function implies interaction between different substances leading to an enhancement of the function or the generation of new substances responsible for the active and intelligent function, only one application covering all the substances that compose the component should be submitted.
An application for the whole active or intelligent material or article should not be submitted.

The guidelines of EFSA describe the required information to be included in the application[1].

[14] EFSA Guidelines on submission of a dossier for safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food. EFSA Journal (2009) 1208, 2-11.

4.7 What is a valid application?

It is an application for a substance covered by the scope of the Union list accompanied by the following documents:

- the name and address of the applicant;
- a technical dossier containing the information specified in the EFSA guidelines for the safety assessment of a substance;
- a summary of the technical dossier.

Also, the information and documents submitted must comply with the EFSA guidelines[15].

The EFSA is responsible for checking the validity of the applications and will send a letter to the applicant to inform him/her whether the application is valid or not. The fact that an application is considered to be valid should not be seen as a pre authorisation in any case; that will depend on other factors, including the risk assessment to be performed by EFSA.

4.8 What is the "initial authorisation phase" prior to establishment of the Union list?

We are currently in the initial authorisation phase for establishment of the first Union list (See part 3). The application period for this phase ran from 14 August 2009 until 14 February 2011. This phase will end when the Commission has adopted a measure establishing the Union list of substances that may be used in active and intelligent components.

Before the Commission adopts the Union list, the EFSA has to issue an opinion on each valid application that was submitted before 15 February 2011. The EFSA has finished checking whether the applications received are valid or not. (Please see question 4.7. for information on what constitutes a valid application).

After receiving all opinions from EFSA on all these valid applications submitted until 14 February 2011, the Commission will submit for opinion to the Standing Committee on the Food Chain and Animal Health a draft measure establishing the Union list.

Annex I gives a schematic outline of the establishment of the Union list of substances to be used in active or intelligent components.

4.9 What is the "register of valid applications"?

It is a publicly available register[16] updated by the Commission. It lists all the processes for which a valid application was submitted before 15 February 2011.

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.

4.10 I have submitted an application before 15 February 2011 but I do not see it in the register of valid applications

A large number of applications have been received, and the EFSA has not yet had time to examine all applications or the Commission is in the process of preparing the register. Your application may be one of those still waiting to be checked.

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[15] http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

[16] The register will be available on the Sanco website Food Contact Materials Section Documents: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

4.11 I have not submitted an application before 15 February 2011.

4.11.1 Can I still submit an application? What is the timeframe for risk assessment and adoption?

Yes. Applications can be submitted after 14 February 2011. However, they are not considered during the initial authorisation phase (see question 4.8). Once the Commission has established the Union list after the EFSA has delivered its opinion on all substances included in the register of valid applications (see part 3 and question 4.9.) (Article 8(6) of Regulation (EC) No 450/2009) these applications will be considered for addition to the Union list.
EFSA will consider the validity of most of these applications at the time the Union list is established. However, if an application was received shortly before the establishment of the Union list, or in case EFSA has requested supplementary information within a time limit, such applications could be considered valid only later (having verified that the information and documents submitted by the applicant are valid).

For such applications, the EFSA must complete its risk assessment within six months after the application has been considered valid. The deadline of 6 months can be extended by a further six months, but in that case the EFSA must explain to the applicant, the Commission and the Member States the reason for the delay. If the EFSA asks the applicant to provide further information, the time limit is suspended until that information is provided (Articles 9, 10 and 11 of (EC) No 1935/2004).

For the addition of new substances to the Union list, an amendment to the Union list needs to be adopted. The procedure laid down in Articles 9, 10 and 11 of Regulation (EC) No 1935/2004 shall apply (Article 8(7) of Regulation (EC) No 450/2009).

Annex I gives a schematic outline of the establishment of the Union list of substances to be used in active or intelligent components.

4.11.2 Should I stop the production of this active and intelligent material or article?

No, you can continue placing on the market the active and intelligent material or article until the date of application of the Union list if you comply with the applicable legislation. However, as from the date of application of the Union list, only active and intelligent materials and articles that comply with compositional requirements can be marketed as set in Art 4(e) and 5.

4.12 Which rules are applicable during the initial authorisation phase?

At present, Commission Regulation (EC) No 450/2009 applies. However, the provisions on compositional requirements of active and intelligent materials and articles (Articles 4(e) and 5) apply only as from the day of application of the Union list. Until that date, national provisions in force concerning the composition of active and intelligent materials and articles continue to apply.
The placing on the market of active and intelligent materials and articles labelled in accordance with Art. 4(5) of Regulation (EC) No 1935/2004 prior to 19 December 2009 is permitted until the exhaustion of stocks.

4.13 I submitted an application before 15 February 2011 but my application was considered not to be valid.

Question 4.7 explains when an application is valid.

4.13.1 Can I submit a new application?

If your substance is not a released active substance, depending on and taking into account the reasons for rejection of your first application, you can submit a new application for the same substance to be used in active and intelligent material or article. As your application was considered non valid it will not be included in the register and not considered during the initial authorisation phase for establishment of the Union list. This new application would then be treated as any other new applications which arrived after the deadline of 14 February 2011 (see question 4.9.1).

4.13.2 Should I stop the production of this active and intelligent material or article?

No, you can continue placing on the market the active and intelligent material or article until the date of application of the Union list if you comply with the applicable legislation. However, as from the date of application of the Union

list, active and intelligent materials and articles have to comply with compositional requirements as set in Art 4(e) and 5. (See also part 3).

4.14 Does the EFSA authorise substances to be used in active and intelligent materials and articles? What is the value of an EFSA opinion?

No, the EFSA does not authorise substances: it performs a risk assessment of the substances. In each opinion, the EFSA says whether or not a particular substance or component complies with the safety criteria laid down in the EU legislation.
The body responsible for authorising the substances is the European Commission. The Commission will refuse or grant their authorisation on the basis of the EFSA opinion, relevant provisions of EU law and other legitimate factors.

4.15 An applicant has submitted a valid application during the initial authorisation phase and the EFSA asked the applicant to provide additional information before a certain deadline. The applicant has not provided that information at all or not in time. What are the consequences?

In that case the EFSA will not continue the risk assessment, and the application will be excluded from consideration for the establishment of the Union list.
The applicant can submit a new application. This new application would then be treated as any other new applications which arrived after the deadline of 14 February 2011 (see question 4.11).

4.16 Is there a deadline for EFSA to perform the risk assessment?

During the initial authorisation phase, for the establishment of the Union list, the EFSA must complete its risk assessment within six months after the application has been considered valid. This deadline can be extended by a further six months, but in that case the EFSA must explain to the applicant, the Commission and the Member States the reason for the delay. If the EFSA asks the applicant to provide further information, the time limit is suspended until that information is provided (Articles 9, 10 and 11 of (EC) No 1935/2004).
For risk assessments to be performed for the addition of substances to the established Union list the same deadline applies for EFSA.

Annex I gives a schematic outline of the establishment of the Union list of substances to be used in active or intelligent components.

4.17 If the EFSA publishes a positive opinion on my substances / component, when will it be authorised by the Commission?

The Commission has no specific deadline for adopting the measure establishing or amending the Union list of substances to be used in active and intelligent materials or articles.
The Commission will adopt the first Union list after the EFSA has delivered its opinion on all substances for which a valid application was submitted before 15 February 2011.

4.18 How much time will it take for the Commission to establish the Union list after EFSA has issued its Opinion on all substances for which a valid application was submitted before 15 February 2011?

Regulation (EC) No 450/2009 does not set a timeframe for adoption of the Union list by the Commission.

4.19 Which legislation applies to the materials and articles that are no active materials and articles?

On the DG Sanco website on food contact materials, an overview of the EU legislation on food contact materials can be found. This is the link: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/spec_dirs_en.htm.

The Framework Regulation (EC) No 1935/2004 lays down the general requirements for all food contact materials. Also Regulation (EC) 2023/2006 on Good Manufacturing Practice for materials and articles intended to come in contact with food applies.

Legislation on specific materials also exists for plastics, recycled plastics, ceramics, and regenerated cellulose film and active and intelligent materials and articles.

For the groups of materials and articles for which no specific requirements at EU level exist, national legislation applies.

4.20 In my view as applicant it is ambiguous whether my application falls under the definition of either active and intelligent food contact materials, or either of plastic food contact materials. Since this may only become fully established during the risk assessment, what can I do to ensure my material is considered for authorization for plastics in case it is not considered an active and intelligent material or article?

The applicant is recommended to mention the following in his request letter sent to the National Contact Point:

"In the case that the application does not fall under the definition of active and intelligent materials and articles, please consider this application as separate applications for the substances [list substance names and CAS numbers] under the authorisation scheme of substances to be used in food contact plastics. For the intended application, these substances require authorization under Article 5(2) of Regulation (EU) No 10/2011 if not part of an active component."

Annex I

Schematic outline
Establishment of the Union list of substances to be used in active or intelligent components