

Review

New EU regulation aspects and global market of active and intelligent packaging for food industry applications

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ABSTRACT

Active and intelligent packaging is based on a deliberate interaction of the packaging with the food and/or its direct environment to improve food quality and safety. Such technology includes advances in delayed oxidation and controlled respiration rate, microbial growth, and moisture migration. Other examples are carbon dioxide absorbers/emitters, odour absorbers, ethylene removers and aroma emitters, while intelligent packaging include time–temperature indicators, ripeness indicators, biosensors and radio frequency identification. Until 2004 in Europe there was a legislative lack for these kind of packaging decreasing their penetration in the EU market. To face the problem Regulation 1935/2004/EC and more specifically Regulation 450/2009/EC set new legal basis for their correct use, safety and marketing. Nevertheless, due to its deliberate interaction with the food and/or its environment, the migration of substances could represent a food safety concern.

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1. Introduction

Traditional food packaging is meant for mechanical supporting of otherwise non-solid food, and protecting food from external influences (Robertson, 2006). This principal function of packaging involves retardation of deterioration, extension of shelf-life, and maintenance of quality and safety of packaged food. Packaging protects from environmental influences causing deterioration of foods

and beverages (Marsh & Bugusu, 2007) such as heat, light, the presence or absence of moisture, oxygen, pressure, enzymes, spurious odours, microorganisms, insects, dirt and dust particles, gaseous emissions, and so on. Prolonging shelf-life involves application of various strategies such as temperature control; moisture control; addition of chemicals such as salt, sugar, carbon dioxide, or natural acids; removal of oxygen; or a combination of these with effective packaging (Robertson, 2006). Other major functions of packaging include containment, convenience, marketing, and communication. Containment involves ensuring that a product is not intentionally spilled or dispersed. The communication function serves

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as the link between consumer and food processor. It contains mandatory information such as weight, source, ingredients, and now, nutritional value and cautions for use required by law. Product promotion or marketing by companies is achieved through the packages at the point of purchase (Kotler & Keller, 2006). Secondary functions of increasing importance include traceability, tamper indication and portion control (Marsh & Bugusu, 2007). It is well known that the key safety objective for these traditional materials in contact with foods is to be as inert as possible, i.e., there should be a minimum of interaction between food and packaging. On the other hand, new food packaging technologies developed during past decades as a response to consumer demands or industrial production trends towards mildly preserved, fresh, tasty and convenient food products with prolonged shelf-life and controlled quality (Lagaron, Català, & Gavara, 2004). In addition, changes in retailing practices (such as market globalisation resulting in longer distribution of food), or consumers way of life (resulting in less time spent shopping fresh food at the market and cooking), present major challenges to the food packaging industry and act as driving forces for the development of new and improved packaging concepts where a useful interaction between packaging, environment and food occurs (Ahvenainen, 2003; Ahvenainen & Hurme, 1997). This is the basic concept of active and intelligent packaging, although due to its deliberate interaction with the food and/or its environment this technology poses new challenges to the evaluation of its safety as compared to the traditional packaging, i.e. migration of substances from packaging to food, incorrect use of the packaging due to the insufficient labeling, non-efficacious operation of the packaging, etc. (Hotchkiss, 1995; Rosca & Vergnaud, 2007).

To this regard, the European Union's Regulation 1935/2004 offered for the first time the opportunity for active packaging to be used in Europe by allowing the application of materials with agents that could migrate into foods. This Regulation regarding all materials and articles intended to come into contact with food contains also general provisions on the safety of active and intelligent packaging and sets the framework for the European Food Safety Agency (EFSA) evaluation process; only in 2009 the new Regulation 450/2009/EC can be considered a measure that lays down specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation 1935/2004/EC for their safe use. This new regulation could represent a partial answer to the lack of penetration of active and intelligent packaging in the European market in comparison to Japan, USA and Australia, where more adequate and flexible regulations permitted in past years technological innovations in the food packaging sector.

The aim of the present work regards the new legal aspects introduced by the recent Regulation EC 450/2009 considering also the global market of active and intelligent packaging applied in food and beverage sector.

2. Active and intelligent packaging: definitions and main characteristics

Definitions stated in Regulation 1935/2004/EC and in Regulation 450/2009/EC consider *active materials and articles*: "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 (Brody, 2001; Floros, Dock, & Han, 1997). On the other hand, *intelligent materials and articles* means: "materials and articles which monitor the condition of packaged food or the environment surrounding the food".

It follows that the purpose of the active packaging is the extension of the shelf-life of the food and the maintenance or even improvement of its quality, while the purpose of intelligent packaging is to give indication on, and to monitor, the freshness of the food (Han, Ho, & Rodrigues, 2005). There are many different types of active and intelligent materials and articles (Ozdemir & Floros, 2004; Rooney, 2005). Substances responsible for the active or intelligent function can be contained in a separate container for instance in a small paper sachet or that the substances can be directly incorporated in the packaging material. Hence, an important objective here is to design functional materials that include the active agent in their structure and that this active substance can act or be released in a controlled manner (Coma, 2008). Moreover, this benefits packagers by simplifying handling, and improves consumer safety by eliminating the potential of accidentally consuming a sachet. Moreover, the active and intelligent materials and articles may be composed of one or more layers or parts of different types of materials, such as plastics, paper and board or coatings and varnishes.

Considering active packaging, they includes additives or 'freshness enhancers' that can participate in a host of packaging applications and by so doing, enhance the preservation function of the primary packaging system. Active packaging includes additives that are capable of scavenging or absorbing oxygen, carbon dioxide, ethylene, moisture and/or odour and flavor taints; releasing

Table 1

Examples of active packaging applications for use within the food industry.

Absorbing/scavenging properties	Oxygen, carbon dioxide, moisture, ethylene, flavors, taints, UV light
Releasing/emitting properties	Ethanol, carbon dioxide, antioxidants, preservatives, sulfur dioxide, flavors, pesticides
Removing properties	Catalysing food component removal: lactose, cholesterol
Temperature control	Insulating materials, self-heating and self-cooling packaging, microwave susceptors and modifiers, temperature-sensitive packaging
Microbial and quality control	UV and surface-treated packaging materials

Table 2

Applications of active packaging technologies.

Type of application	Foods
Oxygen scavengers	Ground coffee, tea, roasted nuts, potato chips, chocolate, fat powdered milk, powdered drinks, bread, tortillas, pizza, pizza crust, refrigerated fresh pasta, fruit tarts, cakes, cookies, beer, deli meats, smoked and cured meats, fish, cheese
Carbon dioxide absorbers	Ground coffee
Carbon dioxide emitters	Meat, fish
Moisture absorbers	Dry and dehydrated products, meat, poultry, fish
Ethylene scavengers	Kiwifruit, banana, avocados, persimmons
Ethanol emitters	Bread, cakes, fish
Antimicrobial releasing films	Dry apricots
Antioxidant releasing films	Cereals
Flavor absorbing films	Navel orange juice
Flavor releasing films	Ground coffee
Color containing films	Surimi
Anti-fogging films	Some fresh fruit and vegetable packages
Anti-sticking films	Soft candies, cheese slices
Light absorbers	Pizza, milk
Time-temperature indicators	Microwaveable pancake syrup, refrigerated pasta, deli items
Gas permeable/breathable films	Ready-to-eat salads
Microwave susceptors	Ready-to-eat meals

oxygen, carbon dioxide, moisture, ethanol, sorbates, antioxidants and/or other preservatives and antimicrobials; and/or maintaining temperature control (Table 1). The wide diversity of active packag-

Table 3
Examples of some currently known active packaging systems (Ozdemir & Floros, 2004).

Type of active packaging system	Substances used and mode of action
Oxygen scavengers	Enzymatic systems (glucose oxidase–glucose, alcohol oxidase–ethanol vapor) Chemical systems (powdered iron oxide, catechol, ferrous carbonate, iron–sulfur, sulfite salt–copper sulfate, photosensitive dye oxidation, ascorbic acid oxidation, catalytic conversion of oxygen by platinum catalyst)
Carbon dioxide absorbing/emitting	Iron powder–calcium hydroxide, ferrous carbonate–metal halide
Moisture absorbing	Silica gel, propylene glycol, polyvinyl alcohol, diatomaceous earth
Ethylene absorbing	Activated charcoal, silica gel–potassium permanganate, Kieselguhr, bentonite, Fuller's earth, silicon dioxide powder, powdered Oya stone, zeolite, ozone
Ethanol emitting	Encapsulated ethanol
Antimicrobial releasing	Sorbates, benzoates, propionates, ethanol, ozone, peroxide, sulfur dioxide, antibiotics, silver–zeolite, quaternary ammonium salts
Antioxidant releasing	BHA, BHT, TBHQ, ascorbic acid, tocopherol
Flavor absorbing	Baking soda, active charcoal
Flavor releasing	Many food flavors
Color containing	Various food colors
Anti-fogging and anti-sticking	Biaxially oriented vinylon, compression rolled oriented HDPE
Light absorbing/regulating	UV blocking agents, hydroxybenzophenone
Monitoring	Time–temperature indicators
Temperature controlling	Non-woven microperforated plastic
Gas permeable/breathable	Surface treated, perforated or microporous films
Microwave susceptors	Metallized thermoplastics
Insect repellent	Low toxicity fumigants (pyrethrins, permethrin)

Table 4
Examples of intelligent packaging applications for use within the food industry (Ozdemir & Floros, 2004).

Tamper evidence and pack integrity	Breach of pack containment
Indicators of product safety/quality	Time–temperature indicators (TTI's), gas sensing devices, microbial growth, pathogen detection
Traceability/anti-theft devices	Radio frequency identification (RFID) Labels, tags, chips
Product authenticity	Holographic images, logos, hidden design print elements, RFID

Table 5
Intelligent packaging systems for food applications.

Indicator	Principle/reagents	Gives Information about	Application
Time- temperature (external)	Mechanical Chemical Enzymatic	Storage conditions	Foods stored under chilled and frozen conditions
Oxygen (internal)	Redox dyes pH dyes Enzymes	Storage conditions Package leak	Foods stored in MA packages
Carbon dioxide (internal)	Chemical	Storage conditions Package leak	MA or CA food packaging
Microbial growth (internal)	pH dyes All dyes reacting with certain metabolites (volatiles or nonvolatiles)	Microbial quality of food	Perishable foods

ing devices have specific applications to individual food products for which the shelf-life can be extended substantially, so long as the food's unique spoilage mechanisms are understood and controlled. Many studies can be found, regarding either application to food industry of active packaging (Table 2) (Kerry, O'Grady, & Hogan, 2006; Kruijff et al., 2002; Labuza & Breene, 1989; Vermeiren, Devlieghere, Beest, Kruijff, & Debevere, 1999) or active packaging technologies (Table 3) (Curcio et al., 2009; Devlieghere, Vermeiren, & Debevere, 2004; Lange & Wyser, 2003; Lopez-Rubio, Almenar, Hernandez-Munoz, Lagaron, Català, & Gavara, 2004; Rooney, 1995; Rooney & Han, 2005; Smith, Daifas, El-Khoury, Koukoutsis, & El-Khoury, 2004; Spizzirri et al., 2009).

Intelligent packaging is packaging that in some way senses some properties of the food it encloses or the environment in which it is kept and which is able to inform the manufacturer, retailer and consumer of the state of these properties (Table 4). Intelligent packaging is an extension of the communication function of traditional packaging, and communicates information to the consumer based on its ability to sense, detect, or record external or internal changes in the product's environment. Basically, there are two types of intelligent packaging: one based on measuring the condition of the package on the outside, the other measuring directly the quality of the food product, i.e. inside the packaging. In the latter case there is direct contact with the food or with the headspace and there is always the need for a marker indicative of the quality and/or safety of the packed food. Examples include time–temperature indicators (TTI), gas leakage indicators, ripeness indicators, toxin indicators, biosensors, and radio frequency identification (Stauffer, 2005; Yam, Takhistov, & Miltz, 2005) (Table 5). Although distinctly different from the concept of active packaging, features of intelligent packaging can be used to check the effectiveness and integrity of active packaging systems (Hutton, 2003; Kerry, O'Grady, & Hogan, 2006).

Among emerging technologies nanocomposite packages are predicted to make up a significant portion of the food and beverage packaging market in the near future, although not yet widely widespread (Ray, Easteal, Quek, & Chen, 2006; Weiss, Takhistov, & McClements, 2006). Some of the applications associated with nanotechnology include improved taste, color, flavor, texture and consistency of foodstuffs, increased absorption and bioavailability of food or food ingredients (nutrients), and the development of new food-packaging materials with improved mechanical, barrier and antimicrobial properties (Chawengkijwanich & Hayata, 2008; Rhim, Hong, Park, & Ng, 2006; Rhim & Ng, 2007). Nanoscale technologies also are in development to improve traceability and monitoring of the condition of food during transport and storage. Improvements in fundamental characteristics of food-packaging materials such as strength, barrier properties, antimicrobial properties, and stability to heat and cold are being achieved using nanocomposite materials (Lagaron, Cava, Cabedo, Gavara, & Gimenez, 2005). Other applications include carbon nanotubes or nanosensors. The first are cylinders with nanoscale diameters that can be

used in food packaging to improve its mechanical properties, although it was recently discovered that they may also exert powerful antimicrobial effects (Kang, Pinault, Pfefferle, & Elimelech, 2007), while nanosensors could be used to detect chemicals, pathogens, and toxins in foods (Liu, Chakrabarty, & Alocilja, 2007).

3. Global market of active controlled and intelligent packaging

Packaging is an essential component market that affects virtually every industry. Each product, even organically grown foods, needs some sort of packaging during its existence for protection during transportation, handling, storage and use. This translates into 99.8% of all food and beverage items that are at one time encased in some sort of packaging. For this reason, the food and beverage industry is continually evolving with new technologies that enhances the quality of the products, prolongs shelf-life, and positively impacts the profitability of a product by reducing waste and spoilage.

Over the past decade, active and intelligent packaging have experienced significant growth and change as new products and technologies have challenged the *status quo* of the traditional forms of food and beverage packaging (Kotler & Keller, 2006). Firstly introduced in the market of Japan in the mid 1970s, active and intelligent packaging materials and articles, only in the mid 1990s raised the attention of the industry in Europe and in the USA.

The global market for food and beverages of active and intelligent coupled with controlled/modified atmosphere packaging (CAP/MAP) increased from \$15.5 billion in 2005 to \$16.9 billion by the end of 2008 and it should reach \$23.6 billion by 2013 with a compound annual growth rate of 6.9%. The global market is broken down into different technology applications of active, controlled and intelligent packaging; of these, CAP/MAP has the largest share of the market estimated to comprise 45.4% in 2008, probably decreasing slightly to approximately 40.5% in 2013 in Fig. 1.

The current US market for active, controlled and intelligent packaging for foods and beverages at over \$54 billion in sales (Table 6) comprising 55–65% of the \$130 billion value of packaging in the United States (Lord, 2008). From reported data is possible to underline, that the need for active, controlled and intelligent packaging has experienced explosive growth over the past decade in the US and is poised to increase at an AAGR of 9.7% between 2003 and 2008. The rest of the world, which has often been ahead of the US in researching and developing new active, controlled and intelligent packaging systems, continues to lead. Growth will be fueled by the development of new generations of products with improved performance at more cost-competitive prices, which will spur greater market acceptance for many product types. The majority of active and intelligent packaging technologies are still

Table 6

US and rest of the world active, controlled and intelligent food and beverage packaging sales up to 2008 (\$ billion).

	2002	2003	2004	2008	AAGR% 2003–2008
US	30.75	34.13	38.13	54.18	9.7
Rest of the World	41.50	46.90	53.00	80.00	0.3
Total	72.25	81.03	91.13	134.18	0.6

specialty niches in the broad US packaging sector due to the relatively high cost of many product types.

Active packaging will comprise approximately 27% of the global market in 2008 but will decrease slightly to 26.9% by 2013. This segment will be worth an estimated \$4.6 billion in 2008 and should reach \$6.4 billion by 2013. Among different typologies, the fraction of active packaging products continues to be developed and to find some commercial applications. In the food and beverage market, growth of active packaging concepts is being driven by the growing use of packaged food, increasing demand for ready-prepared foods such as microwave meals, and increasing use of smaller package sizes. Drivers include consumer desires for food safety, quality, freshness and convenience, as well as packaging users' desire for increased shelf-life. Active packaging is used more heavily in Japan, but use in Europe and North America is beginning to increase (Fig. 2). Active packaging leaders included oxygen scavengers, moisture controllers and a more active role for ethylene absorbers to help reduce the pathogens and gases that contribute to food spoilage, although also UV blocking packaging are forecast to show relatively high growth rates. Edible films and coatings were also highly contributory to the total. In particular oxygen scavenger packaging, in 2005 was the largest segment, accounting for 37% of the global market for active packaging by value while the second largest additive-based segment was moisture scavengers, accounting for 16% of market value.

Intelligent packaging represented a \$1.4 billion segment in 2008, increasing to \$2.3 billion over the next five years. Intelligent packaging works with active packaging on many levels; it provides a safety net with such systems as TTI, embedded microchips and transparent polymers and radio frequencies that identify the status of the food throughout the supply chain. The intelligent packaging sector has been led by scan-code and electronic article surveillance (EAS) technologies. However, new advances in radio frequency technology that integrate into the older systems are rapidly on the rise, propelling many of the technologies used in intelligent packaging to more aggressive growth and market share positions. Gains will be based in next years, on the emergence of lower cost time-temperature indicator (TTI) labels as well as the growing awareness of these products as critical tools in improving food

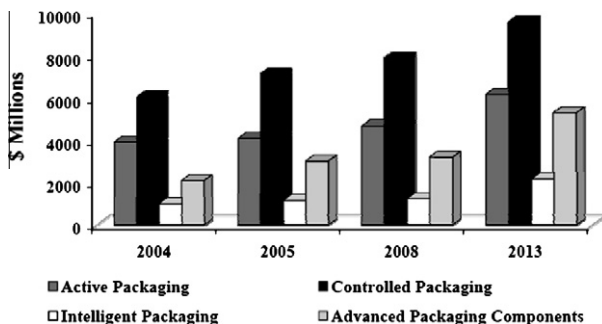


Fig. 1. Growth of active, controlled, and intelligent packaging for the food and beverage industry 2004–2013 (\$ millions).

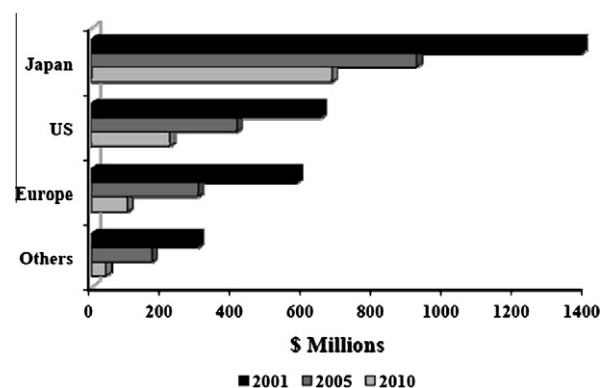


Fig. 2. Global markets for active packaging 2001–2010 (Anon. August, 2007).

safety and reducing losses in perishables from temperature abuse in the supply chain. Increasing cost-competitiveness will support strong opportunities for other intelligent packaging, such as compliance monitoring packaging for pharmaceuticals, active pharmaceutical reminders, ripeness detecting labels, and thermochromic labels.

Considering the diffusion of active and intelligent packaging in EU market, it should be mentioned that the issues of acceptance by user industries as well as the more conservative behaviour of European consumers regarding innovations in food, are key points that still need to be addressed. Low diffusion in EU countries of active and intelligent packaging has been related to two main reasons (Dainelli, Gontard, Spyropoulos, Zondervan-van den Beuken, & Tobback, 2008): the first is cost and the second is acceptance. Considering costs, it is obvious, that they costs will drastically be reduced with broader application and thus scaling-up of production. Discussions are ongoing as to whether consumers will be ready to pay the extra costs for the extra safety/quality tools (Lähteenmäki & Arvola, 2003). About acceptance, often consumers do not perceive active and intelligent materials as a strong benefit. In a study carried out by PIRA International, both brand owners and packaging converters identified as main resistance to the introduction of these materials in the market the fact that the existing materials were considered already adequate to the market needs. Food producer, consumer and retail acceptance will be needed to enable an introduction on a large scale. To this regard, in the Actipack project, consumers' attitudes were investigated in a number of European countries, showing that most consumers are open to innovations in this area provided the material is safe and the information is unambiguous for the user (Actipak, 2001).

Furthermore, consumers are demanding food-packaging materials that are more natural, disposable, potentially biodegradable, as well as, recyclable. For this reason, there is a growing interest in the study and development of renewable source-based biopolymers able to degrade via a natural composting process for antimicrobial active packaging applications (Cha & Chinnan, 2004; Chiellini, 2008; Kumar, Mudliar, Reddy, & Chakrabarti, 2004; Lopez-Rubio et al., 2004; Petersen et al. 1999; Spizzirri et al., 2010). The application of this kind of technologies for designing new commercial products could probably contribute to raise consumers acceptance.

4. Legal issues: US and Europe perspective

The European and United States regulatory concepts about food-contact materials differ not only in detail but in fundamental approach (Heckman, 2005). The European approach is one that is based on the theory that all materials should be explicitly cleared and publicized in regulations, and that all clearances must be based on a toxicological evaluation of the listed substances. In the United States, substances that may not reasonably be expected to become components of food, or that are not likely to give rise to any public health problem, are cleared (or deemed not to require regulation) on the basis of analytical chemistry data and extrapolations that show such components present no cause for toxicological concern because of minimal dietary exposure. In short, the US approach gives considerable credibility to the idea that “the dose makes the poison” so that toxicological justification is not needed, or is greatly minimized by exposure assessments, while the European approach starts from the principle that there must be toxicological data on all substances regardless of the level of anticipated exposure.

Considering regulatory requirements for new active and intelligent packaging technologies, it must be said that in the United States they are not very different from the requirements for con-

ventional packaging materials. Materials used in food-contact applications are subject to premarket regulatory clearance by the US Food and Drug Administration if they are deemed “food additives” under the Federal Food, Drug, and Cosmetic Act. Section 201(s) defines a “food additive” as a substance that is reasonably expected to become a component of food under the intended conditions of use. Because the safety of a substance used in a packaging material is based on the dietary exposure resulting from the intended use, it is irrelevant whether the material is designed to create a protective barrier to prevent against external source contamination. In fact, as long as the material in the active or intelligent packaging system is intended neither to add any substance to the food, nor to have a technical effect in the food (so-called “indirect additives”) there are no special regulatory concerns for substances that are used in such systems; thus, they are simply regulated like all other food-contact substances. If, on the other hand, the active packaging material is added directly to food, or has a technical effect in the food, the material would constitute a “direct additive” and would be subject to much stricter FDA regulatory requirements. While no additional regulatory concerns exist for additives used in active packaging, it is important that manufacturers account for any additional migrants, decomposition byproducts, or impurities that may occur as a result of the chemical activity in the active packaging material during its storage and shelf-life. This information is needed before one can assess whether the material in the active packaging system constitutes a “food additive”.

While active and intelligent packaging is not subject to any special regulatory concern in the United States, the regulation of such packaging material in Europe is still evolving (Fig. 3). Initially, all European food-contact legislation originated in, and was applied in, individual member states. However, with the formation of the European Union, member states elected to harmonise legislation in order to create a single market and overcome complications and barriers to trade. So far, the EU legislation on materials in contact with foodstuffs has protected the health of consumers by ensuring that no material in contact with foodstuffs can bring about a chemical reaction which would change the composition or organoleptic properties of these foodstuffs (taste, appearance, texture or even smell). Regulation 1935/2004/EC repeals this legislation in order to allow packaging to benefit from technological innovation. This was necessary in the EU because all packaging materials (including those that intentionally add substances to food) are subject to all requirements for food-contact materials, including the overall migration limits (OMLs) and specific migration limits (SMLs).

The EU approach to establish a new classification between A&I packaging and the rest of food-contact materials has been critically commented by Heckman in 2007 as an attempt for commercial reasons and not to fill a regulatory gap. It is stated that this purpose could be accomplished in the normal way by the use of marketing techniques, such as special labeling, public education, or advertising. Moreover it is suggested that trying to do so by adding regulatory complications where there is no public interest requirement is of questionable value, and should be avoided because it is useful only to grant governments the right to impose added responsibilities in areas where none are necessary.

4.1. Regulation 1935/2004/EC

The Framework Regulation authorize the use of active and intelligent packaging, provided the packaging can be shown to enhance the safety, quality and shelf-life of the packaged foods. Article 1 notes that the purpose of the law is to secure a high level of protection of human health and protect the interests of consumers so that the Regulation is to be applied to all materials and articles

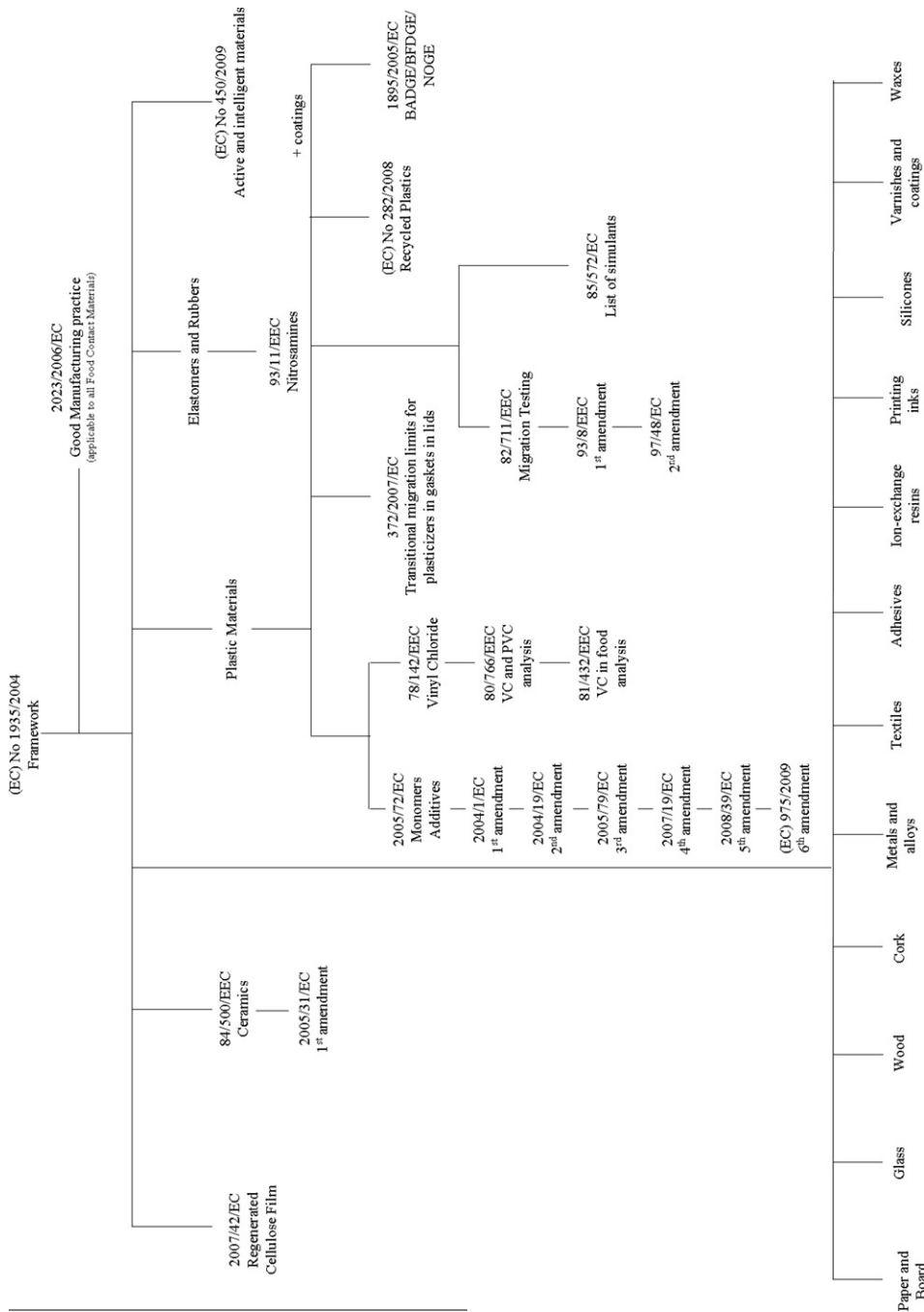


Fig. 3. EU food-contact materials legislation.

(including active and intelligent packaging), which in their finished state are intended to contact food, or can reasonably be expected to contact food, or transfer their constituents to food under normal or foreseeable conditions of use. Article 3 entitled “general requirements” is particularly important because sets forth the proposition that manufacture of all materials or articles be in accordance with good manufacturing practice so that they do not transfer their constituents to food in any quantity that could endanger human health or bring about any organoleptic change or deterioration of the food. Releasing systems are however allowed to change the composition of the food, providing that the released substance is an authorized compound. Labeling should comply with the food additive directive; moreover the release or absorption of substances should not mislead the consumer.

Article 4 is devoted to a discussion of the special requirements applied to active and intelligent packaging, including the requirement that neither sort of system be used to adversely affect organoleptic characteristics of foods or mask spoilage. A labeling provision, presumably to inform consumers that such packaging has been used for a specific food, is also set forth.

All passive parts of active and intelligent packaging systems are also subject to pre-existing European and national food-contact material regulations under the principle of mutual recognition, e.g. plastics, ceramics, etc. For example, the so-called Monomers Directive (Directive 90/128/EEC) and its several amendments, regulates food-contact articles composed entirely of plastic; because many active and intelligent packaging systems are used in packag-

ing materials composed entirely of plastic, the requirements set forth in the Monomers Directive should be met. In particular, the Monomers Directive establishes a purity standard by requiring that no more than 60 mg/kg of substances from the finished plastic article can migrate to food (OML) as well as SMLs included in subsequent amendments. They both should be considered for compliance evaluation.

In addition, some of the systems may also be subject to regulations on food additives, biocides, labeling, environment/waste, modified atmosphere, food hygiene, safety, weight and volume control (a gas absorber or releaser can theoretically influence the volume of a packed food product).

Anyway, the main aspect of the new Regulation is that all new active and intelligent packaging systems initially need to be evaluated by the European Food Safety Authority. Based on the outcome of that evaluation, the Commission (DG SANCO) will grant a petitioner authorisation for the submitted active and intelligent ingredients/systems, which will be entered in the Regulation (Fig. 4). The authorisation is not “general” but is only for the petitioner (“Authorisation holder”). The authorisation of active and intelligent components have to be granted in accordance with Articles 7–9 of Regulation 1935/2004/EC, upon submission of application. Application shall comprise a technical dossier containing specified information and EFSA shall give an opinion within 6 + 6 months providing an explanation for the delay.

Article 15 provides authority to require suitable labeling where needed to advance traceability or safety of use; it contains a great deal of detail about multi-language labeling and what the states can do to accomplish any local labeling purposes. Article 16 requires declarations of compliance with the Regulations, and the making of all data available to competent authorities; it allows Member States to prescribe their own provisions as to declarations of compliance. Article 17 orders that all materials and articles be labeled or otherwise identified so that traceability can be accomplished.

4.2. Regulation 450/2009/EC

General requirements stated in Regulation 1935/2004/EC for the safe use of active and intelligent packaging have been recently integrated by Regulation 450/2009/EC. The new Regulation establishes specific requirements also for the marketing of active and intelligent materials and articles intended to come into contact with food. It is mentioned that the substances responsible for the active and intelligent functions can either be contained in separate containers (e.g. oxygen absorbers in small sachets) or directly be incorporated in the packaging material (e.g. oxygen absorbing films). Moreover, the materials may be composed of one or more layers or parts of different types of materials, such as plastics, paper and board as well as coatings and varnishes. In contrast with active packaging systems, intelligent packaging systems should in no way release chemicals into the packaged food. Intelligent systems may be positioned on the outer surface of the package or be separated from the food by a barrier (functional barrier). Only the active and intelligent “components” should be subjected to authorisation. “Active component” means a system based on individual substance or combination of substances which cause the active function of an active material or article. It may release substances or absorb substances into or from the packaged food or the environment surrounding the food. It means that, for example iron oxide and other substances relevant for oxygen absorption have to be included for authorisation, while packaging of “active components” unless crucial for functioning of system should be not considered. The community list of authorised substances that can be used to manufacture an active or intelligent component of active and/or intelligent materials and articles, shall therefore be estab-

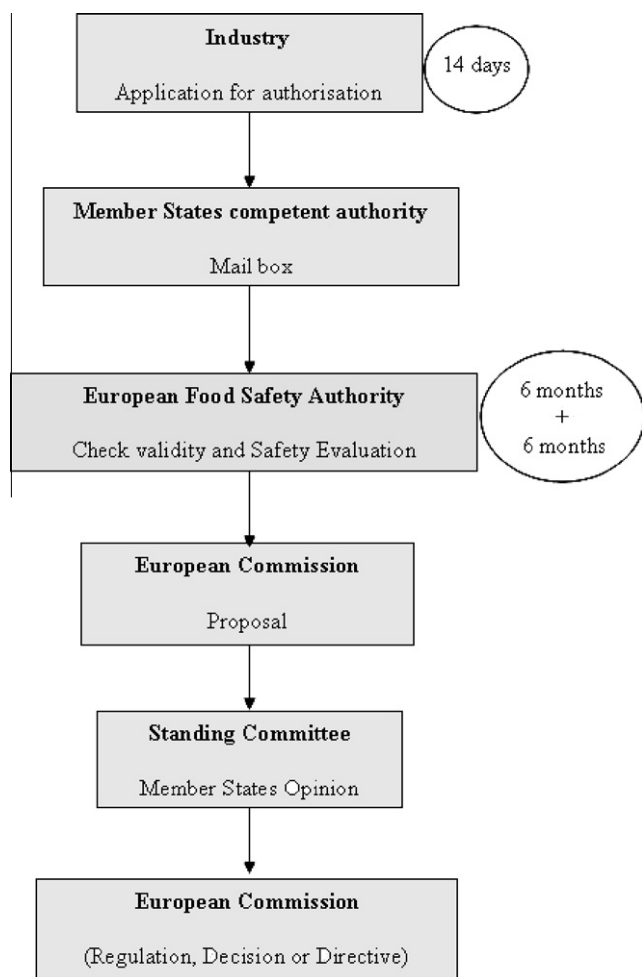


Fig. 4. Authorisation procedure as defined by Reg. 1935/2004 EC.

lished after the European Food Safety Authority (EFSA) has performed a risk assessment and has issued an opinion on each substance. EFSA guidelines explain which factors the authority will take into account when making safety assessments. This includes for example the products' toxicological properties and the extent to which they, or their breakdown products, could transfer into foods. EFSA safety assessment will focus on three risks related to the dietary exposure of chemicals. Those include:

- migration of active or intelligent substances;
- migration of their degradation and/or reaction products;
- their toxicological properties.

Moreover, for each application supporting documentation should be present proving that:

- the information of the intelligent packaging is correct;
- the active packaging has the intended effect on the food.

After reviewing the document, the authority says it will issue an opinion, recommendations, specifications or restrictions on the substance or substances under review and the authorisation is valid for 10 years (renewal necessary). The Regulation allows for an initial 18 month period during which time information on active and intelligent materials and articles should be submitted by applicants. During this period EFSA will accept applications for active and intelligent products that are already on the market; this window is due to close on 21 January 2011.

Passive parts should be covered by the specific community or national legislation applicable to those materials. In this case, if a releasing active component is incorporated into plastic materials, or any other food-contact material covered by a specific Community measure, there may be a risk of exceeding the overall migration limit due to the release of the active substance. Two exceptions are considered in this case: "as the active function is not an inherent feature of the passive material, the amount of released active substance should not be calculated in the value of overall migration". Moreover, specific migration of released active substance can exceed the SML provided that its concentration in food complies with the applicable food law.

Another Framework Directive (89/107/EEC) addresses the regulation of (direct) food additives. This legislation applies to active and intelligent packaging to the extent that substances are intentionally released from the packaging system or have a technical effect on the food. Active packaging systems that intentionally release substances into the package must comply with the (direct) food additives legislation (Regulation 1333/2008/EC), i.e., the released substance must be listed in the positive lists of additives and the use of the substance must accomplish a technological need. As long as intelligent packaging systems are not designed to intentionally release substances into or onto food, Directive 89/107/EEC does not apply to such systems. It follows that, substances deliberately incorporated into active materials and articles to be released into the food or the environment surrounding the food, do not need to be listed in the Community list (article 5(2)(a) of Regulation 450/2009/EC). They shall be used in full compliance with the relevant Community and national provisions applicable to food, and shall comply with the provisions of Regulation 1935/2004/EC and its implementing measures.

On the contrary, non-intentionally migrating substances from active packaging must meet the requirements of Article 3(1) and 4(1) of Regulation 1935/2004/EC and their absence of migration into food have to be duly substantiated. Moreover substances used may not be "carcinogenic", "mutagenic" or "toxic to reproduction" (as listed in Annex I to Council Directive 67/548/EEC; or using the self-responsibility criteria according to the rules of Annex VI to

Directive 67/548/EEC). The same shall apply to substances which are incorporated in active materials and articles by techniques such as grafting and immobilisation, in order to have a technological effect in the food. However, for these substances already approved in food legislation, their stability under the intended packaging manufacturing and processing conditions must be verified by the packaging manufacturer and a dossier for safety evaluation has to be submitted if chemical reaction, degradation or decomposition of these substances is likely to occur.

EFSA guidelines do not apply to substances used behind a functional barrier as defined by Article 3 of Regulation 450/2009/EC (i.e., "functional barrier" means a barrier consisting of one or more layers of food-contact materials which ensures that the finished material or article complies with Article 3 of Regulation 1935/2004/EC and with Regulation 450/2009/EC). Substances behind such a barrier will not, by definition, migrate in amounts which could endanger human health or bring about unacceptable changes in the composition of the food or of its organoleptic properties. Consequently, these active and intelligent substances do not need a safety evaluation and are also outside the scope of Regulation 450/2009/EC. It follows that behind the functional barrier non-authorized substances may be used, provided they fulfil certain criteria and their migration remains below a given detection limit (for infants and other particularly susceptible persons the migration of non-authorized substances through the functional barrier should not exceed 0.01 mg per kg food).

When applying nanotechnology, it is stated they can not be used without further assessment, even when direct contact with the packaged food is impossible through the functional barrier (article 5(2)(c)ii of Regulation 450/2009/EC). Nanoparticles should be assessed on a case-by-case basis until more information is known about this new technology (maximum migration of 0.01 mg per kg).

Finally, labeling must meet the requirements of Regulation 2004/1935, Directive 79/112/EEC (Framework Directive for Sale of Foods) and Directive 89/109/EEC (Labeling of Food Additives); the Regulation requires that from 19 December 2009, to allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts thereof must be labeled, whenever they are perceived as edible: (a) with the words 'DO NOT EAT'; and (b) always where technically possible, with the symbol reproduced in Annex I to Regulation EC 450/2009/EC (Fig. 5). This information must be conspicuous, clearly legible and indelible. It must be printed in characters of a font size of at least 3 mm and comply with the requirements set out in Article 15 of Regulation



Fig. 5. Symbol for 'non-edible' parts in food-contact material labeling.

1935/2004/EC. If active substances are released by the material or article they must be listed as ingredients of the foodstuff.

4.3. Risk assessment and compliance

The tiered approaches used in the European Union and the USA for the risk assessment of substances in food-contact materials are based on the principle that the amounts of data required to establish safety-in-use depend on the extent of dietary exposure. Tiered approaches are increasingly recognized as sound approaches for chemical risk assessment, which not only offer consumers reasonable certainty of no harm, but also avoid unnecessary toxicological testing and focus scarce risk-assessment resources on substances of potential concern (Barlow, 2009). Although the European Union and United States approaches were developed separately, their tiered testing recommendations are similar. Looking ahead to future challenges in risk assessment of substances used in food-contact materials, there are a number of obvious and immediate challenges, such as what will be the data needs for active and intelligent packaging, or for food-contact materials containing substances that are present in nanoscale form, or for recycled plastics. In particular, the evaluation of active and intelligent packaging is costly and, due to the complexity of these systems, many variables can be introduced into the risk assessment process. Moreover, active packaging and some intelligent packaging technologies currently in use are mainly based on sachet technology. Use of these scavenging sachets suffers from inadequate consumer acceptance and they are not appropriate for liquid foods, as direct contact of the liquid with the sachet usually causes the spillage of sachet contents. In addition, sachets may be accidentally consumed with food or may be ingested by children. Another issue about risk assessment with the antimicrobial agents used in active packaging technologies is the development of antimicrobial resistance (Wignall, Goneau, Chew, Denstedt, & Cadieux, 2008; Yazdankhah et al., 2006). Similarly, concern has been expressed about the use of oxygen scavengers allowing for potential overgrowth of anaerobic pathogenic organisms, especially if the temperature is not kept close to 0 °C (Daifas, Smith, Blanchfield, & Austin, 1999; Smith, Hoshino, & Abe, 1995).

It has been previously reported that the risk assessment of nanoparticles has to be performed on a case-by-case basis. This is necessary because data on toxicity and oral exposure of nanoparticles are currently extremely limited. In addition, the small size of many nanoparticles cause them to take on unique chemical and physical properties that are different from their macroscale chemical counterparts. The large surface area of nanoparticles allows a greater contact with cellular membranes, as well as greater capacity for absorption and migration (Li & Huang, 2008). This implies that their toxicokinetic and toxicity profiles cannot be extrapolated from data on their equivalent non-nanoforms. Exposure to nanoparticles is likely to occur through dermal contact with the packaging material, or ingestion due to the leakage to foodstuff (Li & Huang, 2008); also inhalation of nanoparticles is of particular concern (Carlson et al., 2008). In addition, nanoparticles may migrate into foods from recycled packaging produced from material that contains nanoparticles. Also, nanoparticles may be released into the environment and enter the food chain indirectly (Hoet, Brüske-Hohlfeld, & Salata, 2004).

Anyway, to guarantee the conformity of the used materials the Framework Regulation 1935/2004/EC demands in article 16 the preparation of a declaration of compliance. EFSA guidelines recommend to follow the same tiered approach for toxicity testing requirements as is used for conventional food-contact materials. The written declaration of compliance shall contain the following information: identity of material or article; its range of application; and the confirmation that the material or article complies with the

requirements of the European directives and, when appropriate, with national law. When a functional barrier is used in a multilayer material, the following additional information shall be provided: the identity of the substances of the functional barrier, the date of latest use of the material or article; and the maximum heat treatment (temperature and time) for the article. At each stage of manufacture, processing, and distribution an appropriate technical documentation able to demonstrate the compliance of the material, article or substances with the relevant provisions shall be available. This documentation, shall contain the description and the results of the analysis carried out to demonstrate the compliance of the material and article, and in particular the compliance with quantitative restrictions in the use of the substances such as OML, SML, etc., plus the requirements of the layer(s) constituting a functional barrier, and the requirements set out in Article 3 of Framework Regulation 1935/2004/EC related to the substances migrating in detectable amounts and which are not listed in positive lists.

The declaration of compliance should consist of three sections: summary, administrative part and technical dossier. The technical dossier should include: overview of the application, identity of the active or intelligent substance, its physical or chemical characteristics, the manufacturing process, the intended application, existing authorisations, migration data and toxicological information.

One issue in regards to active packaging is whether the analytical methods used in migration studies can adequately detect and quantify what the consumer would be exposed to, and at what level. Systems outside the packaging need in general no migration testing as there will be a “functional barrier” which reduces the potential migration significantly. Nevertheless, active and some intelligent systems are always in “direct” contact with food. In this case the material incorporating the active or intelligent ingredient shall comply with the conventional rules laid down in the EU Directives (both positive list and migration behaviour should be in compliance).

Generally speaking, the testing of a sample against the EU legislation consist of a number of discrete steps: (a) check the composition against the relevant legislation. All components must be on the positive list and as a result some tests to be performed. For parts of the composition that are not covered by the EU Directives (like colorants, catalysts) it must be proven that they are safe as is required in Article 3 of Regulation 1935/2004/EC; (b) select the simulants and test conditions; (c) perform the relevant tests like overall migrations and the experiments which were the result of the compositional check (specific migrations, residual contents and other tests). The generic approach is shown in Fig. 6. If the

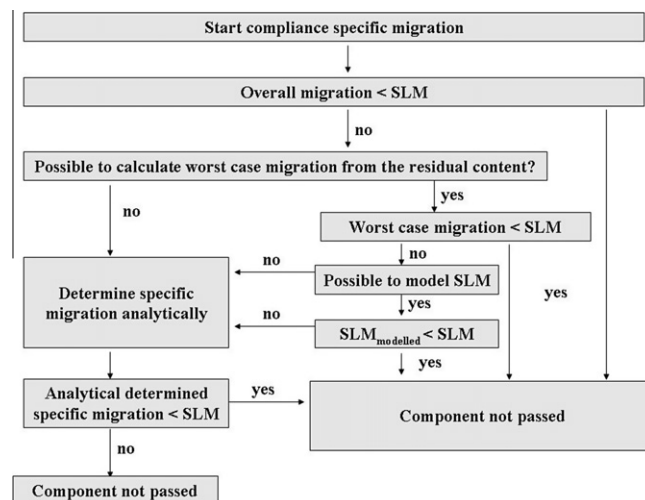


Fig. 6. General scheme adopted for safety assessment applied to every component with a specific migration limit in a food-contact material.

amount of a component that is available to migrate is so small that even if everything were to migrate to the food the migration limit cannot be exceeded, it is clear that the SML cannot be exceeded (worst-case calculation). This calculation can be made using data that are already available like chemical's ingredient specification or the amount of chemical added. As an alternative the residual amount present expressed per unit of area can be determined. If the value obtained is above the specific migration limit mathematical modelling can be used to calculate how much can potentially migrate to the food. Migration data of active and/or intelligent substances and, if any, impurities, reaction products and degradation products, should be provided using, where possible, appropriate conventional migration tests (Barnes, Sinclair, & Watson, 2007), as described in the Dir. 82/711/EEC or dedicated migration/evaluation tests in foods or simulants with demonstrated adequacy for the intended/recommended conditions of use. It has been reported (Dainelli et al., 2008) that new or modified migration protocols may have to be developed and validated to ensure that the studies evaluating packaging technologies employing sachets adequately measure what would migrate to food under actual conditions of use. Alternatively, calculations based on worst case transfer scenarios or recognized mathematical migration models may be used including any assumptions made. Validated analytical methods for the determination of the substances and if relevant their degradation and reaction products in food or food simulants (Dir. 85/572/EEC) and/or in the final material should be given in detail except where the analytical methods used are well established and may be given by reference only (Lopez-Cervantes, Sanchez-Machado, Pastorelli, Rijk, & Paseiro-Losada, 2003). If known, estimates of exposure to the migrating substances from other sources should be provided.

5. Conclusions

A bright future may be anticipated for active and intelligent packaging. To this regard the Regulation 1935/2004/EC and new Regulation 450/2009/EC pose new basis for the general requirements and specific safety and marketing issues related to active and intelligent packaging. Despite long time of commercial use without particular safety concerns, EU regulations seem to be necessary and helpful because they both fit perfectly with the food safety strategy, involving an improved level of food safety and transparency to consumers. In fact, it should be considered that complexity of systems introduce many variables into risk assessment. Pouches/sachets may introduce new migration products and lead to interactions between active agents and other packaging materials. The development and validation of migration tests to reliably detect and measure new migration products could represent a serious challenge, as well as the risk assessment for nanomaterials. Anyway, despite the hurdles that have to be overcome in the near future, there is a strong view that active and intelligent packaging will be a technical tool in the market with a high potential, covering both more transparent communication to consumers and the need for the retail and food industry to better control the food production chain.

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