1
EU Legislation

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1.1
Introduction

The European Union is joining until now 27 sovereign Member States in an alliance that aims, among others, at establishing an internal market and an economic union.

In the area of food safety, measures are being taken to remove trade barriers between the Member States while attaining a high level of health protection. In 2002 [1], the general food law established for the first time in the EU the general principles for food safety covering the whole food chain from farm to fork. Food contact materials play a major role in the whole food chain as they are used in the manufacture of food, such as food producing machinery, they are used to package and enable storage and transport of food, and they are used to consume food, such as tableware. Therefore, legislation is needed to ensure that the materials used to handle or protect food do not become a source of food contamination. The legislation on food contact materials has to be seen in the context of the general food law.

In the area of food contact materials, the first Community legislation was adopted in 1976 laying down the general principles in a Framework Directive [2]. At that time, the Member States had their national legislations on food contact materials and articles, but provisions were divergent and thus were posing a barrier to trade. The adoption of the Framework Directive was the first step in the harmonization of food contact materials legislation. In the meantime, specific Community legislation on certain food contact materials, such as plastics and ceramics, was adopted. As far as most of the specific materials, such as paper or rubber, are concerned, specific rules have not yet been adopted. At the EU level, two types of legislations exist in parallel for food contact materials: harmonized Community legislation adopted by the EU and nonharmonized national legislations adopted by individual Member States.

Therefore, national provisions on specific materials still exist in areas where Community legislation is not yet in place. The rule of mutual recognition applies to this national legislation. Any product lawfully produced and marketed in one Member State must, in principle, be admitted to the market of any other Member State. The only reason a Member State can reject a product is the protection of human health. Even under mutual recognition, a national legislation may foresee that the use of a

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substance lawfully manufactured and/or marketed in another Member State is subject to prior authorization provided certain requirements are fulfilled such as a simplified procedure for including the substance in a national list [3]. In nonharmonized areas, Member States may even adopt new national legislation. This has to be notified to the Commission and must not introduce a new unjustified trade barrier.

1.2 Community Legislation

The Community legislation comprises general rules applicable to all materials and articles laid down in the Framework Regulation (EC) No. 1935/2004 [4] and specific rules only applying to certain materials or certain substances. The two general principles on which legislation on food contact materials is based are the principles of inertness and safety. A general overview is presented in Figure 1.1.

Since 2005, Community legislation can be adopted in the form of a directive, a regulation, or a decision. While a regulation is directly applicable in each Member State, directives have to be transposed into national law with transposition times of up to 18 months. In the past, the 1976 and 1989 Framework Directives required a directive as the legal instrument to adopt the specific implementing measures, but with the new Framework Regulation, regulations have become the preferred implementing measure.

Directives and regulations can be changed and updated by the so-called amendments. These amending directives or regulations include only the changes to the original act but do not repeat the whole text. They follow the same numbering system as the directives or regulations. When a reference is made to a directive or regulation, it is always made to the legal act including its last amendment. Consolidated versions of the directives are usually made available at the Commission web site EURLEX [5]. They consolidate into one text the original directive and the amendments indicating the changes that have been introduced.

The Framework Regulation is adopted by the European Parliament and the Council, while specific directives and regulations are adopted by the Commission after consultation with the Member States in the Standing Committee on the Food Chain and Animal Health. The Commission can adopt only those proposals that gain a qualified majority support of Member States in the Standing Committee, which consists of administrators of the ministries concerned of the Member States.

1.2.1 Horizontal Legislation

1.2.1.1 Framework Regulation

The Framework Regulation (EC) No. 1935/2004 is the basic Community legislation that covers all food contact materials and articles. As a basic framework, it defines food contact materials and articles and then sets the basic requirements for them.

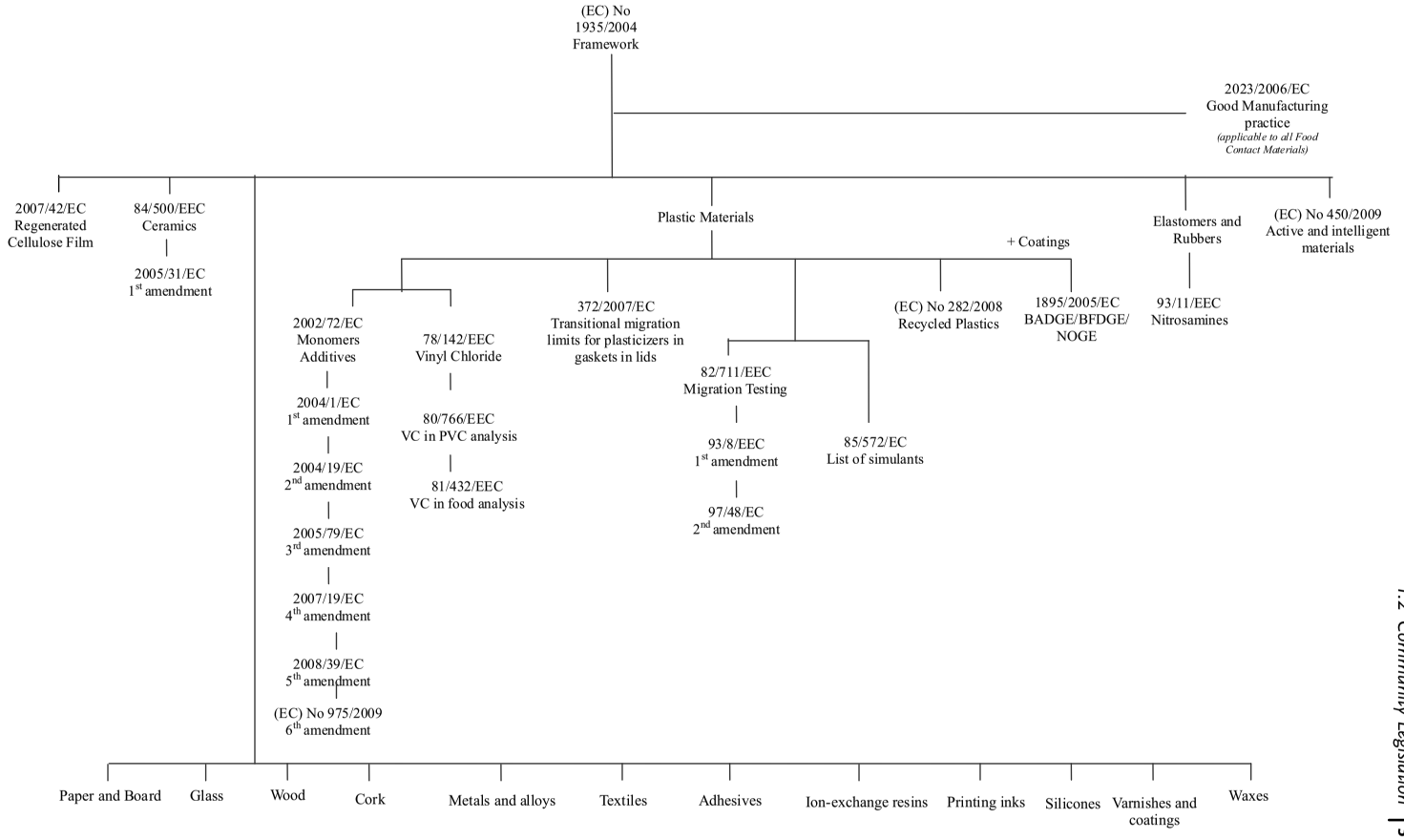

Figure 1.1 Overview of Community legislation (last update October 20, 2009).

Community legislation on food contact materials covers the following products: materials that are already in contact with food such as the packaging of prepackaged food; materials that are intended to come into contact with food, such as cups, dishes, cutlery, and food packaging not yet in use; materials that can be reasonably expected to be brought into contact with food such as table surfaces in food preparation areas or the inner walls and shelves of a refrigerator; and materials that can be reasonably expected to transfer their constituents to food such as a cardboard box around a plastic bag of cereals.

Basic requirements are set to ensure safe food and protect consumer interests. Four basic requirements are set to ensure safe food:

1) food contact materials shall not endanger human health;
2) food contact materials shall not change the composition of the food in an unacceptable way;
3) food contact materials shall not change taste, odor, or texture of the food;
4) food contact materials shall be manufactured according to good manufacturing practice (GMP).

Exemptions from the requirements 2 and 3 are made for active materials and articles (see Section 1.2.3). General rules for good manufacturing practice are laid down in a specific horizontal regulation (see Section 1.2.1.2). Labeling of food contact materials is required to ensure both safety and protection of consumer interests. The consumers, food packer, or converter should be informed on

1) the suitability of the product for food contact (for this purpose, a symbol presenting glass and fork,  , can be used or the words "for food contact");
2) the person responsible for manufacturing or placing on the market of the product;
3) instructions for the safe use of the product;
4) means of identification of the product for traceability.

Traceability is a general obligation derived from the general food law to ensure, for example, retrieval of batches in case of need. Different ways of labeling are possible: on the product itself, on accompanying documents, or at the retailer on a sign near the product. The information that is provided on the label shall not mislead the consumer. If the food contact material is also covered by specific Community legislation, the producer has the obligation to declare that the food contact material used in his product conforms to these specific requirements (see Sections 1.2.2 and 1.2.3). The declaration of compliance of a packaging material, for example, has to contain all information on the product that is necessary for food industry to comply with limits set for certain substances in the food (see Section 1.2.2).

The Framework Regulation empowers the European Commission to set requirements for specific materials. These requirements are specifications of the general rules of the Framework Regulation. These specific requirements can be set for certain types of materials, such as plastic or ceramic, or they can cover only the use of certain substances. Specific requirements can comprise authorization of substances used in

food contact materials, limits on substances used, authorization of manufacturing processes of certain materials, and rules on labeling and compliance testing. The authorization of substances is divided into a risk assessment procedure, performed by the European Food Safety Authority (EFSA), and a risk management decision by the European Commission. At this moment, this authorization procedure applies only to substances used in plastic food contact materials or in regenerated cellulose films that are regulated by a specific measure. A person interested in the authorization of a substance has to submit through a Member State an application including a dossier for safety evaluation by EFSA. EFSA will evaluate the substance following a conventional risk assessment procedure. After consultation with the Member States, the European Commission will, based on EFSA's safety evaluation and taking into account all other relevant factors, take a decision whether to authorize or not the substance. All authorizations granted are general authorizations. This means everybody can use an authorized substance. In principle, the authorization procedure could be adapted, in agreement with the Member States, to authorize the use of substances, materials, or processes only for the individual applicant. Authorized substances are listed in specific Community legislation.

The Framework Regulation contains a list of materials for which specific legislation may be adopted. This list contains 17 different materials. Only a few are yet covered by specific Community legislation (see Sections 1.2.2 and 1.2.3).

1.2.1.2 **Good Manufacturing Practice**

One of the four basic requirements of the Framework Regulation is the application of good manufacturing practice for the production of food contact materials. To ensure a harmonized application of GMP throughout the EU and across the different business sectors, the basic principles of good manufacturing practice are detailed in Regulation (EC) No. 2023/2006 [6]. These requirements are in force since August 1, 2008. GMP has to be applied at all stages of production of food contact materials and articles and in all sectors. Excluded are the stages of production of starting substances and raw materials. For example, for plastic production, the GMP requirements start with the plastic manufacturer followed by the converter including the printing process of the packaging material up to the production of the finished article. GMP starts with the selection of suitable raw materials for which specifications need to be set that ensure the production of a safe finished article. This would, for example, include the control of the purity of the chemicals used. The manufacturing operations have to be specified to ensure that the manufacturing process does not render the final material unsuitable for food contact, for example, by generating unsafe reaction or degradation products. The manufacturing process has to be accompanied by a quality assurance system ensuring that the pre-established criteria are adhered to. The quality assurance system also includes premises and equipment as well as the qualification of the personnel. The critical steps in the manufacturing process need to be controlled by an adequate quality control system including the specification of corrective actions in case of failure. All aspects of the GMP need to be adequately documented and the documentation should be available to control authorities.

Imports from third countries should also conform to GMP. For two applications, GMP requirements have been further detailed: for printing of nonfood contact surfaces and for recycling of plastics. For printing of nonfood contact surfaces, adequate care has to be taken to ensure that constituents of the printing ink are not transferred to the food contact side either via diffusion through the material or via set-off due to direct contact between printed and nonprinted surfaces. The responsibility lies with both the printing industry and the downstream users of the printed articles. For plastic recycling, the quality assurance system shall include quality plans, including those for input and recycled plastic characterization, suppliers' qualification, sorting processes, washing processes, deep cleansing processes, and heating processes.

1.2.2 Specific Measures

The Framework Regulation sets the general principles that apply to all materials coming into contact with food. Details for implementing these general rules taking into account the specific risks of the individual material are given in the specific legislative measures.

1.2.2.1 Plastics

Plastic materials and articles were the first materials to be covered by Community harmonization. The harmonization of the sector is not yet finalized; therefore, provisions applicable to plastic materials and articles exist both at Community level and at national level. Not all Member States have national legislation on plastics. An overview can be found in Section 1.3.

General Requirements in the Plastics Directive

The Directive 2002/72/EC [7] including its amendments covers plastic monolayer and multilayer structures that purely consist of plastic. It also covers plastic layers or coatings that form gaskets in lids. A monolayer structure may be a polyethylene (PE) bag, a multilayer structure may be a plastic tray for prepackaged food consisting of different plastic layers, for example, ethylene vinyl alcohol copolymer/polyethylene (EVOH/PE). Multilayers that consist of plastic and other materials such as plastic-covered paperboard, as in beverage cartons, do not fall under the specific Community legislation on plastics. In this case, national legislation applies. Usually, Member States require that each layer has to conform to the requirements set for the respective materials, while the finished article has to comply with the overall requirement of the Framework Regulation. For these multilayers, compliance with the Framework Regulation is interpreted by most Member States as complying with the migration limits laid down in the plastics Directive.

Plastic coatings, adhesives, and epoxy resins are covered only in part by the specific Community legislation on plastics. Usually, they are used on other substrates rather

than plastic and thus do not fall under the plastics Directive. In addition, monomers and additives used only in plastic coatings, adhesives, or epoxy resins are not listed in the Community lists. Plastic coatings and adhesives are covered by national legislation in some Member States. Plastic coatings containing certain epoxy derivatives are regulated by Regulation (EC) No. 1895/2005 [8] (Section 1.2.3).

Biobased polymers and biodegradable polymers such as polylactic acid (PLA), polyhydroxybutyric acid (PHB), and polycaprolactone (PCL) or starch-based polymers are covered by the Community legislation on plastics.

The general principles laid down in the Framework Regulation are those of inertness and safety. These principles are interpreted in the specific legislation on plastic food contact materials as follows.

The principle of inertness is translated into an "overall migration limit" (OML). The overall migration comprises the total amount of all substances (except water) transferred from the plastic food contact material to the food. The OML is set at 60 milligrams per kilogram of food (mg/kg food). In addition, it has to be ensured that a substance migrating from the food contact material does not exhibit a technological function in the food (unless it is part of an active material, see Section 1.2.3). This may occur if the substance used in food contact materials is at the same time an authorized food additive, for example, antioxidant or preservative. In this case, the migration limit is defined by the amount of substance that does not exhibit a technological function in the food provided any limit on the amount of the food additive permitted in the food is not exceeded.

The principle of safety is translated into specific authorization of substances that are used for the manufacture of plastic materials after their favorable toxicological evaluation by the European Food Safety Authority. A general authorization for the use of the substances is given. Everybody may use the substances respecting the restrictions and specifications given in the authorization, not only the applicant who provided the data for the evaluation. Authorized substances and their restrictions and specifications are published in Community lists annexed to the plastics Directive 2002/72/EC. The list is regularly updated through amendments to the plastics Directive. If necessary for the safety of a material "specific migration limits" (SML) are laid down. The specific migration is the amount of a single substance that may be transferred from the plastic food contact material to the food. The SML is set individually and is based on the toxicological evaluation of the substance. The tolerable daily intake (TDI) of a substance expressed in mg/kg bodyweight is translated into an SML based on a conventional system. This system assumes that 1 kg of food is consumed daily by a 60 kg person. This 1 kg of food is packaged in a plastic material releasing the substance at the level of the TDI. The SML can vary from nondetectable (allowing analytical tolerances) to several milligrams per kilogram food. In cases where only a limited data set is provided for toxicological evaluation that does not allow TDI to be set, specific migration limits are established as follows. If the substance is shown not to be carcinogenic, mutagenic, or toxic to reproduction based on three *in vitro* tests, a specific migration limit of 50 μg/kg food is established. If, in addition, the substance is not toxic in a 90-day long study and is not likely to accumulate in the human body, a specific migration limit of 5 mg/kg food is

established. The migration of a single substance or substances may not exceed the overall migration limit of 60 mg/kg food.

Harmonization of legislation on the substances used in food contact plastics started with monomers as these are reactive substances and thus of primary importance with regard to any potential health risk. Monomers and other starting substances are fully harmonized at Community level. This means that only the monomers listed in the plastics Directive can be used in food contact materials. An exemption exists for plastic coatings, adhesives, and epoxy resins. Monomers that are used only in their manufacture are not listed in the Community list.

In the second step, harmonization of additives used in plastic food contact materials was started. However, this step is not yet finalized. Therefore, additives listed both in the Community legislation and in national legislation can be used in food contact plastics (for national lists, see Section 1.3). Harmonization on additives will be almost finalized by 2010. Until December 31, 2006, all parties interested in Community authorization of additives permitted at national level had to supply EFSA with a valid application for the evaluation of those additives. A provisional list of additives for which a valid application has been received is available on the Commission web site [9]. Additives will be removed from the provisional list if they are being authorized or if a decision is taken not to authorize them or if the applicant did not respect the time limit set by EFSA for submission of additional information. By January 2010, the list of additives annexed to Directive 2002/72/EC will become a positive list. From that date onward, only those additives on that list can be used in the manufacture of food contact plastics. In addition, a substance that is still on the provisional list at that time may continue to be used according to national law until its safety evaluation is finalized by EFSA and a decision on its authorization is taken by the Commission. This Community list on additives contains those additives that are used solely in plastics and those that are used both in plastics and in coatings. However, it does not contain additives used only in plastic coatings, adhesives, and epoxy resins. It also does not include substances used only as polymer production aids. The list does not contain solvents and aids to polymerization, which are not intended to remain in the finished product and colorants.

Impurities, reaction, and degradation products of the authorized substances are usually not evaluated unless listed in restrictions and specifications for the authorized substance. They remain under the responsibility of the producer of the material and article who has to ensure that they do not migrate in quantities that pose a health risk.

Declaration of Compliance

The purchaser of a food contact material should receive an assurance from the manufacturer that the food contact material complies with the applicable legislation. The finished article can be compliant only if throughout the production process requirements of the plastics Directive have been adhered to. Therefore, a declaration of compliance is necessary from the moment a substance, mixture, or plastic is intended for food contact. Each manufacturer has to declare compliance for the

manufacturing steps under his responsibility. For example, a producer of a monomer has to ensure that the monomer is authorized and conforms to the specifications relevant to it. The producer of a plastic has to ensure that monomers and additives are authorized and as far as under his responsibility indicate the conditions of use under which migration limits can be complied with. The manufacturer of the final article has to indicate conditions of use under which restrictions and migration limits can be complied with. The information is, in particular, relevant for the so-called dual-use additives, additives that are used both in plastic manufacture and as food additives. The addition of food additives to food is strictly regulated and it has to be ensured that migration from the food contact materials do not violate those rules of food additives legislation. The manufacturer has to maintain documentation substantiating the declaration of compliance. This documentation has to be available to control authorities on demand.

The Functional Barrier Concept

In multilayer materials, a layer can function as a barrier to migration of substances into food. Since June 2008, when such a functional barrier layer is applied to ensure no migration into food takes place, it will no longer be necessary to authorize the substances used in that layer if those substances are not carcinogenic, genotoxic, or toxic for reproduction. However, the use of the functional barrier concept needs to be declared in the declaration of compliance. Adequate information on the nonauthorized substances used and the demonstration of effectiveness of the functional barrier have to be provided to control authorities on request.

Verification of Compliance with Migration Limits

Analysis of migration from food contact materials can be performed according to different protocols. Verification of the migration limit can be performed on the food itself in case it is already in contact with the packaging material. Verification of migration limits may also be performed on food simulants, usually in case of packaging that is not yet in contact with food. The legislation foresees five food simulants representing different possible extraction properties of food (Directive 82/711/EEC [10] and amendments). These five simulants are water for aqueous food, 3% acetic acid for acidic food, 10% ethanol for alcoholic food, olive oil for fatty food excluding dairy products, and 50% ethanol for dairy products. A correlation list is laid down in legislation that indicates which food is represented by which food simulant (Directive 85/572/EEC [11]). Verification can also be performed by extracting the residual amount of a substance from the food contact material. The residual amount can then either be directly compared with the SML or be subject to mathematical migration modeling giving the migration potential of the application. For proof of noncompliance with SML values, only the migration testing into food and food simulants can be accepted. In cases where the substance is not stable in food or food simulant, the value is expressed as residual content per square decimeter of contact surface (QMA).

Migration testing has to be performed under worst foreseeable contact time and temperature for the envisaged application. A long-term storage at room temperature is, for example, represented by storage for 10 days at 40 °C. A correlation table with migration test conditions is laid down in the legislation (Directive 82/711/EEC). Analytical methods for migration testing of overall migration and specific migration have been standardized at European level by the European standardization body CEN. Information on migration testing can be found at the web site of the Community Reference Laboratory (CRL) for food contact materials [12].

Reduction Factors Applicable in Migration Testing

Two types of correction factors have been established to correct the overestimation of real exposure to or real migration into fatty foods. These are, respectively, the fat consumption reduction factor (FRF) and the simulant D reduction factor (DRF).

When migration limits for substances are set, a conventional system is applied to calculate exposure. It is assumed that a 60 kg person will consume 1 kg of packaged food per day. However, a different convention is sometimes necessary under certain circumstances. One such convention arises in the case of lipophilic substances, which readily migrate into fatty foods. The consumption of fat is usually only 200 g or less per day. For these substances, a reduction factor is therefore established for use in compliance testing, taking into account the lower consumption of fat. A list of substances for which this FRF is applicable is annexed to the plastics Directive.

As migration testing into food is not always feasible, migration testing with food simulants is an alternative to test compliance with migration limits. In particular for fat simulants, the extraction power of the fat simulant (simulant D) is often greater than the expected migration into food that it is representing. Therefore, correlation between foods and fat simulant has been established and on this basis a list of correction factors (D reduction factor) has been created and provided in Directive 85/572/EEC. In case migration testing is carried out in simulant D, both FRF and DRF can be combined to a maximum reduction factor of 5.

1.2.2.2 Recycled Plastics

Recycling of plastic materials has come into focus as the sustainability of production and environmental issues have become more important. As plastic is using up oil resources, targets for recycling plastic packaging waste have been set within the EU. Recycled plastics could qualify as a source for the manufacture of food contact materials provided the strict safety requirements for food contact materials are respected. As the plastics Directive regulates only substances used in the manufacture of plastics such as monomers and additives, the rules laid down therein were not regarded as sufficient to ensure a safe use of recycled plastics in food contact materials. Recycling of used PET beverage bottles into new beverage bottles is increasingly becoming common in Member States. Requirements for the use of recycled plastic in contact with food vary between EU Member States from a ban on authorization schemes to no requirements at all. Some Member States, such as the United Kingdom,

apply the rules for virgin plastics to recycled plastics. EU harmonization of the rules is necessary to ensure an equal treatment to recycled plastics in all Member States.

Therefore, a new approach was developed for using recycled plastics in plastic food contact materials. Two different processes of plastic recycling can be distinguished: in chemical recycling, plastics are depolymerized into monomers or oligomers that are purified and isolated and then used again as starting substances. Monomers and oligomers derived from such chemical recycling need to respect the same safety and purity criteria as identical authorized monomers or oligomers derived from chemical synthesis. For this type of recycling, the requirements of the plastics Directive are regarded as sufficient to ensure product safety. The second recycling process is the mechanical recycling of plastics in which the plastic is simply melted and subjected to certain purification steps. This type of recycling process is not sufficiently covered by the current rules of the plastics Directive and therefore a specific Regulation (EC) No. 282/2008 [13] has been adopted to ensure that products derived from this process can be safely used in food contact plastics. The regulation foresees the individual authorization of the recycling process at Community level based on the safety evaluation of the recycling process performed by EFSA. Critical points in recycling process are the sourcing of the material that is being recycled and the capacity of the process to reduce contamination. Only those plastics that respect the compositional requirements of the plastics Directive can be used as a source for mechanical recycling. As the recycling processes are unique based on the technology used, individual authorization dedicated to the applicant will be issued. All recycling processes shall be accompanied by an adequate quality assurance system that should be audited by Member States. Both recycled plastic and the materials and articles containing recycled plastics need to be accompanied by a declaration of compliance. A transitional phase of 2 years is foreseen during which applications for already existing or new processes can be submitted. All safe processes from this transitional phase will be authorized at the same time at Community level once they all have been evaluated. From the date of this first authorization, only recycled plastics from authorized processes can be used in plastic materials and articles. Subsequent authorizations will follow the adapted general authorization procedure. Until the date of the first Community authorization, national legislation remains in force. The regulation also covers recycled plastics from third countries. Also, these can be used only if the recycling process is authorized. Requests for authorization have to be addressed to a Member State's contact point. Premises in third countries that use the authorized recycling processes have to be notified to the Commission. A level playing field is established for products from third countries and those originating from within the EU.

1.2.3 Other Materials

Specific Community legislation exists not only for plastics but also for some other materials, namely, ceramics and regenerated cellulose film (RCF, cellophane). For rubber teats and soothers, migration of nitrosamines is regulated. For coated materials, plastics, and adhesives, the substances BADGE, BFDGE, and NOGE are

regulated. Specific Community legislation exists for active and intelligent materials, and some general rules for these materials have been laid down in the Framework Regulation.

1.2.3.1 Ceramic Articles

Ceramic articles may pose a risk to the consumer through heavy metals used in glazing and coloring. Substances of major concern in the past have been lead and cadmium. Community legislation (Directive 84/500/EEC [14] amended by Directive 2005/31/EC [15]), therefore, imposes limits for lead and cadmium leaching from ceramic articles into a 4% (v/v) acetic acid solution. Ceramic articles have to be accompanied by a declaration of compliance indicating the manufacturer and importer, if any, as well as the conformity to the limits for lead and cadmium. Rules for migration testing and performance criteria of the analytical method are set in the legislation. For other heavy metals, the general rules of Article 3 of the Framework Regulation apply. Some Member States have national restrictions for some of the other heavy metals and separate limits for migration from the mouth rim of cups and beakers (see Section 1.3).

1.2.3.2 Regenerated Cellulose Film (Cellophane)

At Community level, specific rules for materials and articles made of cellophane exist (Directive 2007/42/EC [16]). Exempted are synthetic casing such as those used for sausages. In these exempted cases, national legislation applies. The legislation contains a positive list of substances that can be used in manufacturing cellophane. The restrictions in the positive list are usually expressed as residual content in the film because migration testing with pure cellophane film into liquid simulant is in general not feasible due to the absorption of water by the film. The positive list does not include dyes, pigments, and adhesives. Substances used for these purposes shall not migrate into food in detectable amounts. From July 29, 2005, the legislation also covers plastic-coated cellophane. For plastic coating, only substances in the list of authorized substances in the plastics Directive (Directive 2002/72/EC as amended) shall be used. The whole film has to comply with overall migration and specific migration limits in the plastics Directive. Analytical methods for compliance testing are published on the web site of the Community Reference Laboratory (http://crl-fcm.jrc.it).

1.2.3.3 Rubber Teats and Soothers

In the 1980s, it became evident that rubber teats and soothers may release carcinogenic nitrosamines, which are reaction and degradation products from accelerators and stabilizers used in the rubber. Legislation contained in Directive 93/11/EEC [17] mandates that nitrosamines and nitrosatable substances that can be transformed into nitrosamines in the stomach shall not be released from teats and soothers in detectable quantities. Methods for analysis are proposed with the detection limit set at 0.01 mg/kg rubber for nitrosamines and 0.1 mg/kg rubber for nitrosatable substances.

1.2.3.4 BADGE, BFDGE, and NOGE in Coated Materials, Plastics, and Adhesives

In the 1990s, high amounts of BADGE (bisphenol A diglycidyl ether) were discovered in fish in oil in tins. The source for the contamination was the coating where BADGE was added as an additive. As the substance contains epoxy groups, it was a suspected carcinogen although it was not considered to be genotoxic, measures were taken to reduce the migration of BADGE from the coating, the plastic, and any adhesive. The measure also covered the replacement products BFDGE (bisphenol F diglycidyl ether) and NOGE (novolac glycidyl ether) that are similar in structure to BADGE. The toxicity of BADGE has now been more thoroughly investigated and studies have clarified that BADGE is not carcinogenic in humans. Toxicity of BFDGE and NOGE is, however, still not clear. The Community legislation takes account of the new toxicological results (Regulation (EC) 1895/2005) and sets a new, higher migration limit for BADGE and its hydrolysis products at 9 mg/kg/food, but for BADGE chlorohydrins it maintains a limit of 1 mg/kg/food. The use of BFDGE and NOGE has been prohibited from January 1, 2005 and March 1, 2003, respectively. Exempted from this ban are heavy-duty coatings in tanks with a capacity greater than 10 000 l and attached tubing. Analytical methods have been developed by CEN.

Although specific to these substances, this legislation has been the first to explicitly set any rules for coatings and adhesives and those plastics that are not within the scope of the rules on food contact plastics. This last point arises from the fact that the legislation covers all plastic materials and articles, not just those within the scope of Directive 2002/72/EC, as amended. A declaration of compliance needs to be issued also for coatings and adhesives with regard to BADGE, BFDGE, and NOGE.

1.2.3.5 Active and Intelligent Materials and Articles

The main function of packaging as regarded in the past was to protect the food from contamination and spoilage and enable the transport of the food. Derived from this concept are the basic principles of food contact materials legislation: packaging should be inert; it should not release substances into food that pose a risk to human health; and it should not release substances into food that change the taste, odor, and composition of the food.

Recent technological developments have made it possible to assign new functions to packaging: it can inform the consumer about the condition of its content and may even interact with the food by releasing or absorbing substances. In view of these additional functions, food contact material legislation was revised in 2004. Two new concepts, apart from inert packaging, have therefore been introduced in the legislation: intelligent food contact materials and active food contact materials. The basic principles of food contact materials have been adjusted in the Framework Regulation to take account of these new features.

Intelligent food contact materials are those that provide the consumer with information on the condition of the packaged food or the atmosphere in the packaging. This information may, for example, indicate storage conditions the food has undergone using time/temperature indicators that turn from green to red when

the food has been stored for a certain time at elevated temperatures. Other examples are indicators for oxygen level in the food or for the presence of microorganisms that spoil the food. The general principle of inertness and the requirements that control substance migration continue to apply to this type of food contact material. However, given the extra function of packaging, it has to be ensured that the information provided to the consumer is not misleading. A freshness indicator, for example, should not misleadingly indicate freshness when the food is already spoiled.

Active food contact materials are those that actively change the composition of the food or its surrounding atmosphere. Two functions have been distinguished: those of absorbers and releasers. Absorbers are constructed such that they absorb substances released by the food or from the atmosphere around the packaged food, for example, oxygen scavengers that reduce the oxygen level around and in the food and thus prevent microbiological growth and reduce oxidation of the food. Releasers are the opposite, they release substances into the food to improve the food or its condition, for example, packaging that releases preservatives into the food. The new now permitted characteristic of the packaging allows to add the active substance to the material to be intentionally released into the food. However, traditional packaging that releases its natural constituent into the food such as wooden barrels used in wine and whiskey production are not covered by the definition of active food contact material, neither are materials to which an antimicrobial substance is added to keep the surface of the material free of microbiological growth. The function in this case is exhibited on the material itself and not on the food. Examples are antimicrobials in chopping boards or conveyer belts.

Thus, in contrast to the traditional concept that food contact materials are inert and perform no intended function on the food, active materials may change the composition of the food, for example, by releasing preservatives, and may change the environment around the food by the absorption of oxygen; they may also change the taste of the food, for example, by releasing flavors; and they may change the color of the food by releasing colorants. To take account of this and to ensure the safe application of the material, the principle of inertness was modified in the Framework Regulation. Active materials may release substances into food but only under certain specified conditions. The substance released has to be a substance that is authorized in the context of food legislation [18], for example, an authorized food additive or an authorized flavoring. The substance may be released only into foods in which it is authorized for release by food legislation; for example, sorbic acid may be added to prepacked sliced bread but not to whole bread. The substance may be released only in quantities authorized in food legislation, for example, sorbic acid 2000 mg/kg prepacked sliced bread. The change in the composition, odor, or taste of the food shall not mislead the consumer about the quality of the food; for example, an absorber may not mask food spoilage and a colorant may not mask poor food quality. Information has to be provided to all operators in the food chain and to the consumer to ensure the correct application of and compliance with food legislation. Therefore, strict labeling rules have been established. The producer of the material has to provide to the food packer information on the identity of the substance used and levels

released. The food packer has to list the released substance in the list of ingredients. Labeling also has to clearly show when active or intelligent materials are used. Nonedible parts of the packaging, for example, absorbing sachets in food packaging, have to be clearly labeled as nonedible.

In addition to these general requirements laid down in the Framework Regulation, additional rules are laid down in a specific measure; Regulation (EC) No, 450/2009 [19] adopted in 2009.

Specific Measure on Active and Intelligent Materials and Articles

Basic requirements for active and intelligent materials have been set in the Framework Regulation that includes provisions for released active substances that have to comply with the food legislation and labeling rules. However, some issues need to be regulated in more detail. These cover in particular the following:

(A) Safety of substances used in active and intelligent materials
(B) Relation to material specific requirements, for example, on plastic food contact materials
(C) Labeling of parts that can be mistaken for food
(D) Declaration of compliance

(A) Safety of substances used in active and intelligent materials

Substances intended to be released into food with an intentional function in the food According to Regulation (EC) No. 1935/2004, substances released into the food need to be authorized and used in accordance with the applicable food legislation. The specific measure confirms and applies this principle. Specific measure clarifies that the same rules and legislation apply if a substance is added directly to the food or via packaging. A duplication of authorization should be avoided; therefore, no authorization scheme would be necessary for these substances in the context of active packaging. Regulation would remain within food legislation.

The following aspect is covered in the specific measure. If legislation on food provides for a limit in food for the "released active substance," the total quantity of this substance in food should not exceed this limit independent of the source from which it derives (released via packaging or added directly to the food). The released substances should be listed in the declaration of compliance (see point D) and adequate information should be given to the consumer or food packer to be able to comply with food legislation. The released substance needs to be listed in the ingredients list.

Substances that contribute to the active or intelligent function but that are not intended to be released into food and that do not have a function in the food These substances have not yet undergone a safety assessment and they might migrate into the food. Therefore, the specific measure on active and intelligent materials applies the

same approach as for plastic materials. These substances should undergo a safety assessment by the European Food Safety Authority and a Community authorization. An authorized substance should then be listed in a Community list (positive list) specifying its identity, function, and, if necessary, conditions or restrictions of use. In certain cases, a combination of substances may be inserted, for example, when the safety assessment is linked to this combination of substances due to their interaction. Once authorized, the substance could be used by all operators provided they comply with the conditions of authorization. Exempted from the Community authorization should be substances that are separated from the food by a functional barrier that reduces migration of the substance to a nondetectable level if the substance is not classified as proved or suspected to be "carcinogenic," "mutagenic," or "toxic to reproduction." As active and intelligent materials are already on the market, it should be provided for a transitional period to set up the Community positive list.

(B) Relation to other material-specific requirements, for example, on plastic food contact materials

The specific measure covers only the component responsible for the active or intelligent function and does not regulate the basic material into which the component is incorporated. This applies not only to ceramics, regenerated cellulose films, and plastics for which specific Community measures exist but also to paper, rubber, metals, and so on that are regulated at the national level. For example, in the case of an active plastic absorber, the plastic material has to be manufactured in accordance with the plastics Directive and the active absorber component would need to be manufactured in accordance with the rules set out in the specific measure. In the particular case of a "releasing active material," if the material-specific measure, for example, the plastic Directive, foresees an overall migration limit, the measured overall migration value should not include the amount of the intentionally released substance.

(C) Labeling of parts that can be mistaken for food

For nonedible parts of active and intelligent materials, in particular, sachets containing substances that can be mistaken for food, the consumer should be informed that they are not for human consumption. The specific measure foresees, for example, labeling with the words "do not eat" and a symbol such as  .

(D) Declaration of compliance

All specific measures should require a declaration of compliance. For active and intelligent materials and articles, the declaration of compliance covers the following aspects. The active and intelligent materials shall not mislead the consumer. Therefore, they need to be effective and suitable. Information with regard to their effectiveness and suitability should be included in the declaration of compliance and demonstrated in the supporting documentation. The declaration of compliance should contain adequate information related to the substances for which restrictions

are in place. This information shall allow the user of the material to ensure compliance with those restrictions. The declaration of compliance should contain adequate information on the released active substances to allow the user to ensure compliance with the restrictions in the relevant food legislation including the labeling requirements of Directive 2000/13/EC.

1.2.4 Control of Food Contact Materials in the EU

The basic rule in the Community food legislation specifies that only safe food shall be placed on the market (Article 14 General Food Law). Consequently, food contact materials should not transfer their substance into the food in concentrations that can endanger human health (Article 3 Framework Regulation). The main players to ensure the safety with regard to food contact materials are the packaging industry, food industry, competent authorities in the Member States, and the European Commission.

1.2.4.1 Role of the Business Operators: Food Industry and Packaging/Contact Material Industry

Both the food industry and the food contact material industry have a shared responsibility for the material in contact with the food and, as a consequence, for the food itself. In the case of food packaging, the food packer has to ensure that only packaging that is suitable for the food is used and that it conforms to the Community and/or national legislation on food contact materials. The packaging industry has to supply packaging that is suitable for food contact. This means that they have to make sure that substances they use in the food contact material are authorized (if positive lists exists) and/or are not transferred into food in concentrations that pose a danger to human health. They have to confirm this in a declaration of compliance. An intensive dialogue between the two parties is, therefore, essential for the compliance of the legislation to be achieved.

The food business operator has the obligation to withdraw unsafe food from the market and to collaborate with the national control authorities on that (Regulation (EC) No. 178/2002 – General Food Law). The European Commission has published guidelines to help business operators to comply with this obligation [20].

1.2.4.2 Role of the Member States

Member States have the responsibility of enforcing the Community and their own national legislations and must ensure that the legislation requirements are fulfilled by business operators (General Food Law). Inspection and control measures on food contact materials shall be carried out according to the Regulation (EC) No. 882/2004 on official feed and food control (OFFC) [21]. In the OFFC, it is specified that control of the application of the rules on materials and articles in contact with food is within its scope. Member States are required to carry out official controls

regularly and with appropriate frequency that should be based on the level of assessed risk. The controls shall include those on materials and substances including those covering food contact materials. They shall equally treat products for EU and the local market, as well as imports and exports. The official control can cover the following actions: monitoring, surveillance, verification, audit, inspection, sampling, and analysis. The text explicitly mentions inspections of materials and articles in contact with food. Member States have to lay down a catalog of sanctions and measures including dissuasive penalties for nonconformity with the food legislation. The measures taken by Member States may include prohibition of placing on the market, order and monitor withdrawal of goods from the market, and recall and destruction. Furthermore, they have the right to detain consignments from third countries.

When Member States take measures that affect other Member States, such as withdrawal from the market when the article originates from, or is distributed to, another Member State, they should inform the Commission and the other Member States via the electronic Rapid Alert System for Feed and Food (RASFF). Other Member States affected by their action are then also able to act.

Member States have to lay down their control activities in multiannual control plans from 2007.

1.2.4.3 **Role of the European Commission**

The European Commission's Food and Veterinary Office carries out Community controls in Member States and in third countries in order to check their national control systems. On food contact materials, desk studies on the systems in place have been performed in all Member States. An inspection of the national control system on food contact materials has been undertaken in several Member States and in China.

1.2.4.4 **Methods for Sampling and Analysis in the Official Control**

The OFFC Regulation establishes a hierarchy of methods used for sampling and analysis in applying official controls. First priority is given to methods laid down in Community legislation. If these do not exist, methods according to internationally established rules such as those of CEN or those in national legislation should be applied. In the absence of these methods, other methods fit for the purpose or developed in accordance with scientific protocols shall be used. In the area of food contact materials, analytical methods are laid down in Community legislation for vinyl chloride in PVC and food, lead and cadmium leaching from ceramic ware, nitrosamines and nitrosatable substances in rubber and food, as well as rules for migration testing. The majority of methods in the area are standardized CEN methods covering migration testing procedures (series EN1186) and the analysis of specific migrating substances (series EN13130) [22]. Examples of methods laid down in national legislation are the methods according to §64 of the German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch [23].

Other methods not used in the context of official controls such as those used for in-house control purposes may be single laboratory validated according to internationally accepted protocols (e.g., IUPAC harmonized guidelines). General criteria for the characterization of methods of analysis exist.

In order to achieve uniformity in the application and the performance of laboratories in the official control, a system of Community Reference Laboratory (CRL) and National Reference Laboratories (NRLs) was established. This system became fully functional in 2006 with the laboratory on contact materials at the Joint Research Centre IHCP in Ispra acting as CRL. The CRL provides national control laboratories with harmonized analytical methods and coordinates the Network of NRLs to favor exchange of information, capacity building, and training.

1.3 Specific National Legislation

Community legislation was introduced to harmonize national legislation and to remove trade barriers. A Member State's legislation is based on different principles and this can still be observed in those areas that are not yet covered by Community legislation.

Four main legal systems can be distinguished.

1) **Premarket approval system**: This system was applied by some new member states. All materials and articles had to be approved by a central authority before they could be placed on the market. This system no longer exists.
2) **System of authorized substances and migration limits comparable to the Community system**: This system was applied in the Netherlands (warenwet) and to some extent in France and Italy. It still exists for those specific areas where no Community legislation is yet in place.
3) **System of recommendations and quantities of substances recommended to be used in the finished material or article**: This system is applied in Germany (BfR recommendations).
4) **System of no specific legislation but industry code of practice defining due diligence of the business operators**: This system is applied in the United Kingdom.

Most of the 27 Member States do not have specific national rules, newer EU Member States replaced their national legislation with Community legislation before accession to the EU.

Member States that do not have specific national legislation on food contact materials will sometime refer to other Member State's legislation, such as Dutch warenwet or the German recommendations, when testing for safety compliance. Some Member States may also refer the application of the general safety clause included in the Framework Regulation to the resolutions and policy statements of the Council of Europe. In the area of food contact materials, the Council of Europe can take initiatives in those sectors that are not yet harmonized at Community level.

The Council of Europe is an intergovernmental organization but not an institution forming part of the European Union. The Council of Europe currently has 47 member countries, including all 27 European Union Member States.

Within the Council of Europe, the activities on materials coming into contact with food are delegated to the European Directorate for the quality of medicines and health care. The work of the subcommittee commonly results in resolutions, which act as recommendations to the 18 members of the Partial Agreement, 17 of which are European Union Member States.

Table 1.1 gives an overview of the Member States in which national legislation exists and in which sectors national legislation is applicable. Norway, Iceland, and Liechtenstein, as part of the European Economic Area (EEA), also apply the Community legislation while keeping additional national legislation. Switzerland has adopted regulations corresponding to the Community legislation.

1.4 Future Trends

1.4.1 Plastic

The completion of harmonization of rules for plastic food contact materials and articles is within sight. The near future will bring a codification of the measures on plastics and it is envisaged at the same time to separate explanatory rules on compliance testing into guidelines.

1.4.2 Nanomaterials

In food contact materials, as in other areas, substances may be used in manufacturing materials and articles and added in the form of nanoparticles to increase the functionality of the material. The use of this technology is developing. The challenge for the industry and European authorities is to assess if the migration behavior from the nanomaterial is different from that of traditional materials and whether substances migrating are more reactive and have a different toxicological profile from regular substances. The answers to these questions will determine if specific requirements are necessary for nanomaterials and if there is a need for a specific implementing measure. The EU is developing general strategies on policies on nanomaterials, nanoparticles, and nanotechnology on horizontal level. In the meantime, it should be kept in mind that the safety evaluation of an authorized substance to be used in plastics has not taken into account its toxicological profile in nanoform unless specifically mentioned in the evaluation. According to the Framework Regulation, a business operator using an authorized substance has the obligation to inform the Commission of any new scientific or technical information that might affect the safety assessment of the authorized substance.

Table 1.1 Summary of the national legislation. +: National legislation apply −: No national specific legislation.

Last update	Member States	Other	Adhesives	Ceramics	Glass	Enamel	Metals alloys	Cork	Wood	Textile
07/11/2005	Austria	−	−	+	−	+	−	−	−	−
27/07/2009	Belgium	−	−	−	+	−	+	−	−	−
23/07/2009	Bulgaria	−	−	−	−	−	−	−	−	−
20/08/2009	Cyprus	−	−	−	−	−	−	−	−	−
07/05/2007	Czech Republic	−	−	+	+	+	+	+	+	−
23/07/2009	Denmark	Mandatory registration[a)]	−	+[b)]	+	−	−	−	−	−
07/11/2005	Estonia	−	−	−	−	−	−	−	−	−
07/11/2005	Finland	−	−	−	−	−	+	−	−	−
02/09/2009	France	−	−	+	+	+	+	−	+	−
07/11/2005	Germany	−	+[c)]	+[d)]	+[d)]	+[d)]	−	−	−	−
07/11/2005	Greece	−	−	−	−	−	+	−	−	−
30/07/2009	Hungary	−	−	+	−	+	+[e)]	−	−	−
23/07/2009	Ireland	−	−	−	−	−	−	−	−	−
15/09/2009	Italy	−	−	+	+	+[f)]	+[g)]	−	−	−
23/07/2009	Latvia	−	−	−	−	−	−	−	−	−
14/08/2009	Lithuania	−	−	−	−	−	+	−	−	−
07/11/2005	Luxembourg	−	−	−	−	−	−	−	−	−
07/11/2005	Malta	−	−	−	−	−	−	−	−	−
23/07/2009	Netherlands	−	−	+	+	+	+	+	+	+
07/11/2005	Poland	−	−	+[h)]	−	+[h)]	−	−	−	−
30/07/2009	Portugal	−	−	−	+[h)]	+[h)]	−	−	−	−
15/09/2009	Romania	Yes: colours[e)]	−	−	−	−	−	−	−	−
23/07/2009	Slovakia	−	−	−	+	−	+	+	+	+
04/08/2009	Slovenia	Yes: colours[i)]	+	−	+	+	+	−	+	+
20/08/2009	Spain	Yes[j)]	−	−	−	−	−	−	−	−

(*Continued*)

Table 1.1 (*Continued*)

Last update	Member States	Other	Adhesives	Ceramics	Glass	Enamel	Metals alloys	Cork	Wood	Textile
11/08/2009	Sweden	–	–	–	–	–	+	–	–	–
23/07/2009	UK	–	–	–	–	–	+ [k)]	–	–	–
07/08/2009	Norway	Mandatory registration [n)]	–	+	+	+	+	–	–	–

Last update	Member States	Paper board	RCF	Plastics	Varnish coating	Printing inks	Silicone	Wax	Rubber	Ion-exchange resin
07/11/2005	Austria	–	–	–	–	–	–	–	–	–
23/07/2009	Belgium	+ [o)]	–	–	+ [o)]	–	–	–	–	–
02/10/2009	Bulgaria	–	–	–	–	–	–	–	–	–
20/08/2009	Cyprus	–	–	–	–	–	–	–	–	–
07/05/2007	Czech Republic	+	–	–	+	+	+	–	+	–
23/07/2009	Denmark	–	–	–	–	–	–	–	–	–
07/11/2005	Estonia	–	–	–	–	–	–	–	–	–
07/11/2005	Finland	+	–	–	–	–	–	–	–	–
02/09/2009	France	+	–	+	+	–	–	–	+	–
07/11/2005	Germany	+ [c)]	–	+ [c)]	–	–	+ [c)]	+ [c)]	+ [c)]	–
07/11/2005	Greece	+	–	+	+	–	–	–	–	–
30/07/2009	Hungary	–	–	+	–	–	+ [l)]	–	+ [l)]	–
23/07/2009	Ireland	–	–	–	–	–	–	–	–	–
15/09/2009	Italy	+	+	+	+	–	+	–	+	–
23/07/2009	Latvia	+ [m)]	–	–	–	–	–	–	–	–
14/08/2009	Lithuania	+	–	–	–	–	–	–	–	–
07/11/2005	Luxembourg	–	–	–	–	–	–	–	–	–
07/11/2005	Malta	–	–	–	–	–	–	–	–	–
23/07/2009	Netherlands	+	+	+	+	+	+	+	+	–
07/11/2005	Poland	+ [h)]	–	–	–	–	–	–	–	–
30/07/2009	Portugal	–	–	–	–	–	–	–	–	–

15/09/2009	Romania	–	–	–	–	+[e)]	–	–	+[e)]	–
23/07/2009	Slovakia	+	–	–	+	–	–	–	+	–
04/08/2009	Slovenia	+	–	–	+	–	–	–	+	–
20/08/2009	Spain	–	–	+	–	–	–	–	–	–
11/08/2009	Sweden	–	–	–	–	–	–	–	–	–
23/07/2009	UK	–	–	–	–	–	–	–	–	–
07/08/2009	Norway	–	–	–	–	–	–	–	–	–

a) Mandatory registration for producers and importers of: all materials covered by the GMP regulation and the reference to Regulation (EC) No 1935/2004, Annex I.
b) Also for glass and ceramic products.
c) BfR recommendation.
d) DIN standard.
e) National legislation and standards.
f) Limitation on lead.
g) Specific measures for: stainless steel, tin free steel, tin containers.
h) National standards.
i) Rules on the requirements concerning the hygiene suitability of consumer goods.
j) Polymeric materials legislation, Prohibition of regenerated polymeric material and plastic and sanitary Register for Industries of substances and food contact material Industries.
k) Old legislation from 1972 on cooking utensils.
l) For teats.
m) Paper and cardboard materials and articles can not release more than 0,5 mg cadmium from a kg of paper and not more than 3 mg of lead from a kg of paper.
n) Mandatory registration for all producers, importers and wholesalers of food contact materials.
o) Resolutions (adoption pending).

1.4.3
Risk Assessment

For the majority of materials and articles, specific Community legislation is not yet in place. In the area of plastic materials and articles, monomers and additives are toxicologically evaluated, but possible impurities, and reaction and degradation products are not taken into consideration in the authorization unless they have been evaluated in the risk assessment. Therefore, it is the manufacturer's responsibility to assess and ensure the safety of such substances that migrate from their products. To ensure the safety of the product, the manufacturer should apply scientifically based risk analysis including exposure assessment in those instances where an established migrant into the food is not specifically regulated in law. At this moment, an EU-wide research project is generating data on exposure to food contact materials and is exploring the feasibility of refined exposure assessment in the legislation of food contact materials.

1.4.4
Other Materials

For materials not yet harmonized at Community level, the Council of Europe resolutions could be taken as a basis for discussion on new rules. Paper and board, and coatings and adhesives are the sectors most likely to follow.

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2 Council Directive 76/893/EEC of 23 November 1976 on the approximation of laws of the member states relating to materials and articles in contact with foodstuffs. OJ L 340, 9.12.1976, p. 19.

3 Judgment of the European Court, 5 February 2004, in Case C-24/00.

4 Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27.10.2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L338, 13.11.2004, p. 4.

5 http://eur-lex.europa.eu.

6 Commission Regulation (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. OJ L 384, 29.12.2006, p. 75.

7 Commission Directive 2002/72/EC of 6 August 2002 related to plastic materials and articles intended to come into contact with foodstuffs. Corrigendum OJ L39, 13.02.2003, p. 2.

8 Commission Regulation (EC) No. 1895/2005 of 18 November 2005 on the restriction of the use of certain epoxy derivatives in materials and articles intended to come into contact with food. OJ L 302, 19.11.2005, p. 28.

9 Provisional list of additives available at the following web site: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm.

10 Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. OJ L297, 23.10.1982, p. 26.

11 Council Directive 85/572/EEC of 19 December 1985 framing the list of simulants to be used for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. OJ L372, 31.12.1985.

12 CRL FCM web site: http://crl-fcm.jrc.it/.

13 Commission Regulation (EC) 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with food and amending Regulation (EC) No. 2023/2006. OJ L 86, 28.3.2008, p. 9.

14 Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the member states related to ceramic articles intended to come into contact with foodstuffs. OJ L 277, 20.10.1984, p. 12.

15 Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC with regard to a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs. OJ L 110, 30.4.2005, p. 36.

16 Commission Directive 2007/42/EC of 29 June 2007 concerning the materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. OJ L 172, 30.6.2007, p. 71. (This text codifies Directives 93/10/EEC, 93/111/EC, and 2004/14/EC.)

17 Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the *N*-nitrosamines and *N*-nitrosatable substances from elastomer and rubber teats and soothers. OJ L93, 17.4.1993, p. 37.

18 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the member states concerning food additives authorized for use in foodstuffs intended for human consumption. OJ L40, 11.21989, p. 27, Flavouring Directive, nutritional fortification, ...

19 Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food of L135, 30.5.2009, p. 3–11.

20 http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm.

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