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Legislative issues relating to active and intelligent packaging

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22.1 Introduction

Major technological developments in food packaging can introduce many benefits to consumers and food and food-packaging industries, but at the same time they are liable to the introduction of new problems. Although active and intelligent packaging continues to broaden in scope and these new packaging systems are already being successfully applied in the USA, Japan and Australia, its penetration in the European marketplace has been quite limited thus far. This is partly due to the strict European regulations for food contact materials, which fail to keep up with technological innovations and currently prohibit the application of many of these systems. In addition, a lack of knowledge of consumer acceptance, of economic aspects and of the environmental impact of these novel concepts and, in particular, the lack of hard evidence of their effectiveness demonstrated by independent investigators has inhibited their commercial usage.

Within the Actipak project active and intelligent packaging systems were defined as follows:[1]

- Active packaging actively changes the condition of the packaged food to extend shelf-life or improve food safety or sensory properties while maintaining the quality of the packaged food.
- Intelligent packaging systems monitor the condition of packaged foods to give information about the quality of the packaged food during transport and storage.

In Europe, no specific regulation governing active and intelligent food packaging exists to date. Most active and intelligent agents are not considered

Ahvenainen, R. [ed.]. Novel food packaging techniques. Cambridge : Woodhead publishing limited, 2003, p. 459-496.

as food additives but rather as food contact material constituents, and therefore these food packaging systems should comply with the existing regulations for food contact materials. When these regulations were drafted, no allowance was made for active and intelligent packaging as these systems were not applied as food contact materials in Europe at that time. The current packaging regulations require that all components used for the manufacture of food contact materials are covered by so-called positive lists. These lists of approved compounds usually include components required to manufacture the packaging material. Constituents used for other purposes such as extending or monitoring the shelf-life of packaged foods are not included. Therefore, most active and intelligent agents are not listed. In addition, active and intelligent systems should comply with relevant overall and specific migration limits. The overall migration limit of 60 mg per kg food is a major hurdle to the application of active packaging in Europe, especially when the system is designed to release active ingredients into foods to extend their shelf-life or improve their quality. Moreover, current migration tests are not always suitable for these new packaging systems because the conventional ratio of 6 dm^2 to 1 kg food is generally much smaller and, in addition, they often differ in contact mode from conventional packaging. Therefore, a new approach to food packaging regulations is required, and new migration test methods should be developed and validated for some of these new food packaging systems.

No single European regulation currently covers specifically the use of active and intelligent packaging systems. The food-contact application of active and intelligent packaging systems is covered by a range of EU regulations, each having its specific requirements, such as regulations for food-contact materials, food additives, biocides, modified-atmosphere packaging, hygiene of foodstuffs, labelling and packaging waste. Some of these regulations may be, unintentionally, an obstacle to the introduction of active and intelligent systems in Europe. Therefore, a few years ago, two initiatives were taken to implement active and intelligent packaging within the European regulations.

In 1999, a pan-European project was started within the framework of the EU FAIR R&D programme. The study aims at initiating amendments to European legislation for food contact materials to establish and implement active and intelligent systems within the current relevant regulations for packaged food in Europe.[1, 2] In 2000, a comprehensive report on legislative aspects of active and intelligent food packaging was published by a project group under the Nordic Council of Ministers. The report describes some types of active and intelligent food contact materials, the legislation the project group found to be relevant to consider, as well as some conclusions and proposals for administrators for future work with recommendations and interpretations of existing legislation. Also, the possibility of establishing new specific legislation for active and intelligent packaging is considered.[3] Both initiatives will now be discussed in more detail below.

22.2 Initiatives to amend EU legislation: European project

In 1999, a European study was started to enable the safe application of active and intelligent packaging systems throughout Europe by initiating amendments to European legislation for food contact materials in order to establish and implement these systems in current relevant regulations for packaged food in Europe. The study was entitled 'Evaluating safety, effectiveness, economic-environmental impact and consumer acceptance of active and intelligent packagings' ('Actipak'). The Actipak project was co-ordinated by TNO Nutrition and Food Research and was jointly carried out by nine research organizations and three industrial companies.[1] The research project consisted of five key tasks. The study was completed by the end of 2001. For each task the main results and conclusions are summarized below.

Task 1: Inventory

At the start of the project an overview of all existing commercial and promising but not (yet) commercially available active and intelligent packaging systems was prepared. The review contains information on technology, market trends, consumer needs and current legislation in Europe and relevant countries outside Europe. Part of the review has been described in detail in a separate publication.[2] The main conclusion to be drawn from the review is that no European regulation currently covers the use of active and intelligent packaging. The traditional European regulations for food contact materials, the overall migration limit and lists of approved compounds may be inconsistent with some of the objectives of active and intelligent packaging. In addition, some 25 packaging systems were selected for compositional analysis and overall migration study (Task 2).

Task 2: Classification of active and intelligent systems

In this task the composition and migration behaviour of selected active and intelligent packaging systems were investigated to identify conflicts with current legislation. A total of 20 active systems and 6 intelligent systems were investigated. The composition was investigated in view of the EU positive list and positive lists of national regulations. Determination of the composition focused on active ingredients and relevant reaction products. The compositional analysis of some active packaging systems has been described in detail.[4, 5] Some typical results are shown in Table 22.1.[1]

The compositional analysis revealed that many active and intelligent packaging systems are very complex in composition. Apart from plastics, other materials such as paper, metals, adhesives, printing and minerals are being used. Existing EU legislation for food contact materials such as the EU Directive for polymeric food contact materials (Directive 90/128/EEC and its amendments) applies to only a minority of the materials tested. In addition, the overall migration behaviour of the active and intelligent packaging systems was investigated. Some relevant results of the overall migration study obtained for oxygen scavengers and moisture absorbers

Table 22.1 Composition of some active and intelligent packaging systems[1]

Packaging system	Ingredients identified
Oxygen scavengers	Iron powder Silicates Sulfite Chloride Polymeric scavenger Elements: Fe, Si, Ca, Al, Na, Cl, K, Mg, S, Mn, Ti, Co, V, Cr, P
Antimicrobial releasers	Acids Silicates Ethanol Zinc Elements: Si, Na, Al, S, Cl, Ca, Mg, Fe, Pd, Ti
Indicators	Methylene blue and other colour indicators Acids Antioxidants Mineral oil Sugars Elements: Na, Ca, K, Si, Al, Mg

are presented in Table 22.2.[1] A complete overview of all migration values obtained in this study has been reported by De Meulenaer *et al.*[5] Quite a few migration values obtained exceed the overall migration limit. Some of the high levels observed were supposed to be attributable to the use of inappropriate liquid migration simulants. Solid migration simulants such as agar gels could be an alternative.[6] The three time-temperature indicators were not included in the overall migration study. As the current systems are generally applied on the outside of the packaging and for relatively short periods of time, the packaging material can be considered to be a functional barrier, and therefore migration testing of time-temperature indicators is not relevant.

Based on the results of the evaluation of the composition and the migration behaviour, the active and intelligent systems were classified in view of restrictions of current regulations into five categories (A–E) according to the scheme shown in Fig. 22.1. These categories are:

Category A: Systems that comply with the current legislation (i.e. composition and migration).

Category B: A system belongs to category B if it contains components not listed in the positive lists of the EC (90/128/EEC and amendments) but which are food additives and/or natural components and/or other components of which toxicological data are available. The migration behaviour of the category-B systems is in compliance with the migration limits as set by the EC.

Table 22.2 Overall migration from oxygen scavengers and moisture absorbers[1]

Sample	Type	Test condition	Overall migration (mg/sample) into:						
			Water	3% Acetic acid	10% Ethanol	15% Ethanol	95% Ethanol	Iso-octane	Olive oil
Oxygen scavenger	Sachet	10 days at 40°C 2 days at 20°C	620[b]	1700[c]	–	800[a]	210[c]	1.9[c]	–
Oxygen scavenger	Cap	10 days at 40°C 2 days at 20C	74[c]	98[c]	80[c]	–	43[c]	0.9[c]	–
Oxygen scavenger	Crown	30 min. at 70°C + 10 days at 40°C	1.0[c]	1.7[c]	1.5[a]	–	–	–	27.8[a]
Moisture absorber	Sachet	10 days at 40°C 2 days at 20°C	<0.1[a]	970[c]	–	0.6[c]	2.3[c]	<0.1[a]	–
Moisture absorber	Pad	10 days at 40°C 2 days at 20°C	9.3[b]	46[c]	–	7.2[b]	21[c]	18[c]	–
Moisture absorber[d]	Film	10 days at 40°C 2 days at 20°C	260[a]	300[a]	–	300[b]	8.2[b]	0.1[c]	–

[a] Standard deviation <5% ($n = 3$ or 4)
[b] Standard deviation >5% and <10% ($n = 3$ or 4)
[c] Standard deviation > 10% ($n = 3$ or 4)
[d] Overall migration in mg/dm^2 instead of mg/sample
– Not measured

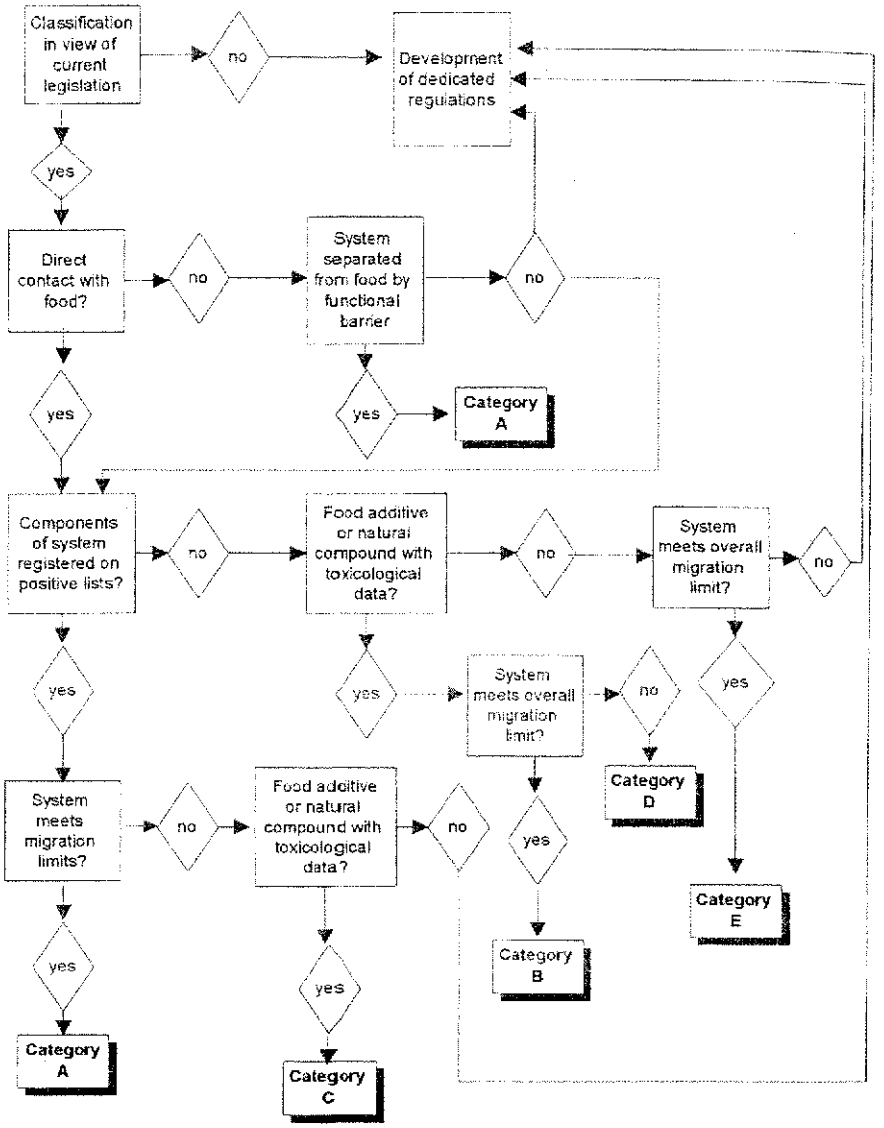

Fig. 22.1 Classification of active and intelligent food-packaging systems in view of current legislation. For a description of categories A–E, see the text (reproduced with permission from Food Additives and Contaminants, July 2002. http:/www.tandf.co.uk).

Category C: These systems contain components that are included in the positive lists of the EC, but the migration exceeds the migration limit(s) set in the current legislation.

Category D: These systems contain components that are not included in the positive lists of the EC but are food additives or natural components or other components for which toxicological data are

available. In addition, the migration from the systems exceeds the migration limit(s) set by the EC.

Category E: These systems contain components that neither are listed nor are food additives or natural components or other components for which no toxicological data are available.

Most of the systems investigated could be classified into categories A and B. Some fall into categories C and D. Only a carbon dioxide-releasing system could not be classified.[5] Generally, it could be concluded that an extension of existing regulations with dedicated requirements seems to be necessary to permit the breakthrough of these materials on the EU market and to guarantee their safe introduction and use in Europe.

The results of the classification have been used to select representative combinations of foods and active and intelligent packaging systems for further validation studies.

An overview of the food-packaging combinations selected for evaluation of microbiological safety, shelf-life-extending capacity and efficacy of the active and intelligent systems is presented in Table 22.3.

Task 3: Evaluation of microbiological safety, shelf-life-extending capacity and efficacy of active and intelligent systems

In this task an overall evaluation of the capability (including effectiveness, safety and shelf-life-extending capacity) of the active and intelligent packaging systems was conducted. To this end, the microbiological safety of the test food, packed and stored in active packaging systems, was determined by analyzing their microbiological condition. In addition, the risk of false indication of intelligent systems was examined. Furthermore, the effectiveness of active

Table 22.3 Food-packaging combinations selected for validation studies

Packaging system	Food
Oxygen-scavenging film	Fresh pasta
Moisture-absorbing film	Fish
Moisture-absorbing pad	Fresh meat
Ethylene-absorbing film	Bananas
Antimicrobial film	Cheese
Antimicrobial film	Meat
Antimicrobial film	Fruit
Aldehyde-absorbing film	Cereal
Oxygen-scavenging sachet	Milk powder
Oxygen-scavenging sachet	Biscuits
Moisture-absorbing sachet	Milk powder
Antimicrobial sachet	Sandwich bread
Oxygen-scavenging crown	Beer
Time-temperature indicators	Fish
Oxygen indicators	Sliced meat
Carbon dioxide indicator	Sliced meat

Table 22.4 Effectiveness and shelf-life extending capacity of some food/active packaging test combinations

Active packaging	Food product	Effective	Shelf-life extension *
Oxygen-scavenging film	Fresh pasta	Yes	Yes, longer microbiological shelf-life not due to O_2 absorption but to barrier characteristics of the active film
Moisture-absorbing pad	Pork	Yes	No, same microbiological and sensory shelf-life
Antimicrobial film	Cheese/ bread	Possibly	No, same microbiological shelf-life
Aldehyde-absorbing film	Cereals	Yes	Yes, longer sensory and chemical shelf-life
O_2-absorbing sachet	Milk powder	Yes	No, but a good alternative (same sensory and chemical shelf-life) to MAP can packaging
O_2-absorbing sachet	Cooked ham	Yes	Yes, longer sensory shelf-life/same microbiological shelf-life
O_2-absorbing crown cork	Beer	Yes	No, same sensorial shelf-life

* Compared with a food/packaging combination without an active packaging system.

packaging systems to improve the microbiological stability of food, as compared to traditional packaging systems, was tested. Also the extension of sensory and chemical shelf-life was investigated for different active packaging/food combinations.

In total, 12 studies were performed to investigate the effectiveness and shelf-life-extending capacity of selected food/active packaging combinations. Some typical results are presented in Table 22.4. Most of the active systems investigated appeared to be effective as claimed by their manufacturers. From the shelf-life studies it can be concluded that a number of active systems indeed prolong shelf-life. The indication capacity of three time-temperature indicators, two oxygen indicators and a carbon dioxide indicator was investigated. The indicators investigated indicated relatively well the conditions they were meant for (time-temperature history, package headspace oxygen or carbon dioxide).

Task 4: Toxicological, economic and environmental evaluation of active and intelligent systems

Intelligent devices and some active systems may contain substances that are not food additives and have not been evaluated by the EU Scientific Committee on Food (SCF) for use in food contact materials. Within the Actipak project it was therefore agreed to study the consequences when a substance is not on the positive list of the directives on food contact materials and to collect and interpret available toxicological data. Examination of existing toxicity data of

one substance with oxygen absorption capacity indicated the substance to be potentially mutagenic. This demonstrates that substances used in active and intelligent packaging systems should be evaluated by SCF before allowing them to come in contact with foodstuffs. In other words, they should be evaluated like all other substances used in food contact materials.

To establish acceptance among European consumers of active and intelligent systems that have been proved to be suitable and safe, these systems were subjected to an international study on consumers' attitudes towards application of these systems. This study also provides insights into national differences and general attitudes. Consumer focus groups consisting of 8–12 people of mixed age and sex were formed in six European countries, namely the UK, Italy, Germany, the Netherlands, Finland and Spain. The results demonstrated that for active and intelligent devices to be readily accepted in Europe in the immediate future, their introduction to the marketplace should be supported by a substantial information campaign clarifying their benefits and how they function. They will not gain acceptance purely by virtue of extension of shelf-life. Also, to avoid confusion, some standardization, at least of indicators, would be preferable. Attitudes are fairly consistent in Europe with the exception of Spain and possibly Italy. Consumers in Spain were much more ready to accept both active devices (absorbers, including sachets) and indicators, and responded very positively to them. Italy also seemed slightly keener than the rest of Europe.

The economic consequences and environmental implications of active and intelligent systems were evaluated as part of the project. The shelf-life-extending capacity of active packaging is expected to reduce food waste due to spoilage. Consequently, energy and packaging materials may be saved. Multi-layer barrier packaging materials might be replaced by less complicated packaging materials, thus reducing packaging waste. In addition, from the study the conclusion can be drawn that the use of intelligent packaging such as time-temperature indicators will decrease the waste generated in the long term.

Task 5: Recommendations for legislative amendments

Finally, all results of the project and the requirements of all relevant EU regulations were evaluated. Based on this evaluation recommendations were drafted for the implementation of suitable active and intelligent systems in relevant European Directives. These recommendations were discussed informally with several national and European authorities. In addition to food packaging regulations, other relevant European regulations were studied such as regulations for food additives, biocides, pesticides, modified-atmosphere packaging, flavouring, food hygiene, labelling, product safety and packaging waste. These regulations generally do not form a serious hurdle to the safe introduction of active and intelligent food packaging systems in Europe. The directive on food hygiene even appeared to be an incentive to the use of active and intelligent packaging.

The first proposal for changing the framework Directive 89/109/EEC has resulted in a draft amendment of the this directive in which active packaging is

included in the scope as described in Article 1. It is expected that this amendment will be approved by the end of 2003. This will remove the first barrier to the introduction of active packaging systems in Europe. A more detailed description of the results of this task will be given in section 22.4.

22.3 Initiatives to amend EU legislation: Nordic report

The Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) have a long tradition of co-operation in the food packaging area, and these countries have similar legislation for food contact materials. A project group under the Nordic Council of Ministers has discussed the legal aspects of active and intelligent systems. The project group was chaired by Dr Fabech of the Danish Veterinary and Food Administration. In 2000, the project group published a report on legislative aspects of active and intelligent food packaging.[3] This so-called 'Nordic Report' aimed at contributing to a solution of legislative problems related to active and intelligent food contact materials. In the first chapter of that report an overview is given of different types of active and intelligent food packaging. The effectiveness of these systems and the test requirements are discussed. The most important part of the report is a comprehensive overview of European legislation relevant to active and intelligent packaging. In section 22.4, a description of these EU directives is given and their relevance to active and intelligent packaging is discussed.

In the Nordic report recommendations are also given as to which parts of the EU legislation should be reviewed and which questions could be solved through interpretation of existing legislation. Preferably, harmonized legislation should be interpreted on a European basis to avoid divergence in interpretation, which could lead to barriers to trade. Proposals are given for solutions to problems by interpretation. According to the Nordic group, it is not necessary to introduce new EU legislation. Instead, amendments should be made to existing legislation and guidelines on how to interpret existing legislation should be given. Finally, initiatives are proposed to be taken by legislators, both on a national and on an EU level, when drafting new or revising existing legislation on active and intelligent packaging.

22.4 Current EU legislation and recommendations for change

For this study of relevant European regulations, a schedule was made of the scope of active and intelligent packaging systems. Definitions of active and intelligent systems are proposed. Based on that principle an overview of the physical appearance of the systems is required as well as a division by functionality of the various systems.

22.4.1 Scope of active and intelligent systems

Active systems

Active packaging systems may differ in appearance. Active packaging systems may be packaging materials to wrap foodstuffs, but may also be added to the packed food in the form of a sachet, label, box, etc. A correct description, which will be used in regulatory amendments, would be 'active food contact material systems'. For practical reasons, the term 'active packaging systems' will be used here.

Conventional packaging materials are considered passive, and their main function is protection against the environment. Active packaging systems intentionally absorb or release substances from or to the food or its environment. Ingredients required to achieve the effect may be incorporated in the packaging material itself or packed in a sachet or label inserted into the package. The total contact area of active packaging systems may be the same as for conventional packaging material, such as a film. But, in case of sachets or labels, the ratio may be significantly smaller than 6 dm^2/kg food. This may influence migration requirements and testing protocols. Both absorption and release of substances should not endanger human health. For this purpose many regulations at the EU and the national level are in force, which should be taken into account to judge the acceptability of an active packaging system.

Intelligent systems

Intelligent systems are only occasionally packaging materials. They usually are packed together, inside or outside the primary packaging, with the food in the form of a label, a pill, etc. As there is potential contact with food they should be called 'intelligent food contact material systems' but, for practical reasons they will be called 'intelligent packaging systems' here.

Intelligent packaging systems provide the user with information on the conditions of the food. Intelligent systems do not influence the food but provide information to consumers, retailers, manufacturers, etc. Intelligent packaging systems should not release their constituents to the food. In many cases a so-called functional barrier, which prevents migration, is present. However, attention must be paid to the fact that intelligent systems may contain all kinds of chemicals required for detection of the intended information. Attention should also be paid to the acceptance of the use of these substances, particularly for packed foods presented directly to the consumer. Starting from the requirement that safety of the food and subsequently safety of the consumer shall never be endangered, the legal restrictions as well as the possibilities for the use of active and intelligent systems were studied in depth. Solutions for existing barriers are proposed.

22.4.2 Identification of relevant regulations

Active and intelligent packaging systems in contact with foods should comply with regulations on food contact materials. In addition, the composition of the

food can be influenced by the use of active packaging systems. The following regulations are considered and further discussed:

- food contact materials
- food additives
- flavouring
- hygiene
- biocides
- pesticides
- labelling
- product safety
- weight and volume
- waste.

22.5 Food contact materials

The requirements for food contact materials (FCM) are formulated in general terms in Framework Directive 89/109/EEC;[7] some materials are regulated in detail in specific directives. Directive 89/109/EEC is under revision and will be published in 2003.

22.5.1 Framework Directive 89/109/EEC

Directive 89/109/EEC specifies the definition of FCM and general requirements. Article 2 requires production of FCM according to good manufacturing practice, while application of FCM shall not endanger human health or change the composition or sensory properties in an unacceptable way. Article 6 describes the requirements for labelling and a demonstration of compliance with specific directives.

Relevance to active and intelligent packaging systems

Undoubtedly, active and intelligent packaging systems are intended to come into contact with food, although some may be separated by a 'functional barrier' from the food. Therefore, active and intelligent packaging systems fall within the scope of framework Directive 89/109/EEC. According to article 2, they shall not endanger human health, nor change the food's sensory characteristics. The latter requirement may be influenced by personal preferences and could be an issue of discussion. In addition, in further specific directives like 2002/72/EC[8] an overall migration limit of 60 mg/kg food is established as a purity requirement. Active systems developed to release certain components most likely will not comply with this requirement. To provide clarity, the scope of Directive 89/109/EEC should be extended to allow intentional migration from food contact materials at levels exceeding 60 mg/kg.

Intentional migration of substances has an effect on the composition of the food. It should be emphasized that the released substances are subject to various relevant regulations pertaining to food ingredients, food additives, labelling, etc. Intelligent packaging systems shall comply with Article 2, so no additional provisions in the framework directive are considered necessary. Specific measures may be required to regulate the chemicals used in the intelligent packaging systems, but this is a subject of specific directives.

Recommendations for extending Directive 89/109/EEC

Based on the results of the Actipak project, amendment of Directive 89/109 has been proposed, and the proposals have been adopted for implementation. A revised Directive will include an extended scope that mentions the allowed use of active and intelligent food contact materials. Special attention will be given to releasing packaging systems. The food in contact with such systems shall comply with any relevant food or food additive regulation. The releasing active packaging systems will be limited to materials that release substances added for that purpose. This means that natural materials, for example wooden barrels for wine or whisky storage, are excluded from the definition of active food contact materials.

Proper labelling will also be required. This includes the conditions (time and temperature) in which the system can be brought into contact with the food and the food that may be in contact with a releasing system. As food additive regulations have to be obeyed the food packer should be informed about the amount of substance released from one object. Annex I of the Directive will be extended with active and intelligent systems. Annex I contains a list of materials, covered by specific measures. This means that in the future a specific directive will be drafted on active and intelligent packaging systems.

22.5.2 Directive 80/590/EEC[9]

Symbol for food contact materials

In Directive 80/590/EEC the symbol to be used for food contact materials not already in contact with foodstuffs is introduced. The symbol shall be used according to the requirements of Directive 89/109/EEC. Alternatively, subjects may be accompanied with the words 'suitable for food contact'.

Relevance to active and intelligent packaging systems

Both active and intelligent packaging systems will not be available to consumers, as they usually require special care before bringing them into contact with foodstuffs. The final user of the A&I systems has to be informed that the subject is suitable for food contact, and thus the systems have to be labelled accordingly. Options are to print the symbol on the system or, at the wholesale stage, to add documentation with this symbol or proper wording. In those cases where a system as such is available to consumers the system should also be labelled in accordance with the requirements of this directive.

Recommendations
Directive 80/590/EEC should be followed. There is no need for amendment of this directive.

22.5.3 Plastics directives

Directive 2002/72/EC sets requirements for food contact materials manufactured solely from plastics. The composition of plastics permitted as food contact materials is based on the principle of a positive list. Maximum allowed migration limits of plastic components are based on the toxicological properties of substances. An overall migration limit of 60 mg/kg food or 10 mg/dm^2 is set to prevent contamination of the food to an unacceptable level.

The directive is intended to harmonize certain classes of substances such as monomers, starting materials and additives. Polymerization regulators are not covered by the directive, but they shall not endanger human health according to framework Directive 89/109/EEC. In some countries, including the Netherlands and Germany, these substances are regulated at a national level. Article 8 of Directive 2002/72/EC requires verification of compliance with the requirements of the directive in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC. In addition, the materials and articles shall be accompanied with a declaration of compliance at the marketing stage rather than the retail stage.

Relevance to active and intelligent packaging systems
Active packaging systems manufactured solely from plastics must comply with the requirements of Directive 2002/72/EC, meaning that composition and migration behaviour must be in compliance with the positive list and the migration restrictions. Active packaging systems, such as some types of oxygen absorbers, based on active ingredients that are incorporated in the backbone of the polymer shall comply with the directive. It is argued that these materials may be used to wrap the food in the same way as conventional packaging materials. This means that all substances used should have been evaluated by the SCF and be added to the positive list with or without a specific migration limit.

Plastic materials and articles containing a substance intentionally released to the food should be treated differently. The base polymer should comply with Directive 2002/72/EC, whereas the released substance should be an approved food ingredient or food additive. Listing of the released substances on the positive list for plastics seems unnecessary as these substances should be allowed as food ingredients or food additives. However, allowance of the presence of such substances should be provided for in the plastics directive. Overall migration from releasing materials or articles may conflict with the overall migration limit. A requirement of enforcement authorities may be the possibility to check the overall migration of the polymer itself. In principle, this could be determined by the classic determination of the overall migration and subsequent subtraction of the specific migration of the released substance. However, in many cases the amount of released substance may be much higher

than the overall migration limit and the analytical error may be even higher than the overall migration limit itself. As a matter of fact, the plastic material can only be verified for compliance if the plastic is available without the releasing substance. This would require either enforcement of the plastic material at an early stage or demonstration of compliance by a reliable and acceptable certification procedure.

Homogeneous intelligent systems manufactured from plastics only (mono- and multi-layers) and in which the intelligent ingredients are immobilized in the polymer backbone or blended as an additive in the plastic should comply with the requirements of Directive 2002/72/EC provided they are intended to come directly into contact with the food.

Two types of composed materials and articles can be identified. First, there are systems that are manufactured by packing the active or intelligent ingredients in a plastic bag or box. Such a system is usually inserted into the primary package with the foodstuff. The plastic part of the system should be in compliance with Directive 2002/72/EC. However, the ingredients packed inside cannot be considered as plastic. These systems should be considered an entity of a food contact material and hence the whole system is excluded from the plastics regulation. Special provisions will be required to include this type of food contact materials.

Systems of a second type are composed of various types of packaging materials, such as plastic, paper, metal, printing, adhesives, varnish and active or intelligent ingredients. Usually the individual components of the final system are hard to recognize. Such composite materials and articles are not covered by Directive 2002/72/EC. It is most likely that no EU regulation exists on the individual parts of the system. Regulations for paper, metal, printing inks and varnishes exist at the national level of some member states, waiting for harmonization at the EU level. This means that these systems are subject to national regulations and to the framework Directive 89/109/EEC. Both for enforcement authorities and for manufacturers this is an uncomfortable situation as it is difficult to establish the safety of these types of food contact materials. It seems realistic to assume that fully harmonized legislation on all types of food contact materials will not be available in the short term.

Concerning active and intelligent ingredients, it was found that some are already included in a positive list, such as iron oxide used in oxygen absorbers, but many others are not. However, all these substances need to be regulated to avoid their use is forbidden without firm grounds and the possibility that unsafe situations may occur. Therefore, if there is direct contact with the food, the system should be submitted to migration testing protocols and the relevant substances should be toxicologically evaluated and subsequently added to a positive list.

Frequently applied intelligent systems, such as time/temperature indicators, are positioned on the outside of the primary food packaging. In addition, these systems are usually made of plastic and connected to the packaging by an adhesive layer. Use of time/temperature indicators almost automatically implies

that storage times are relatively short and temperatures are low. Taking this into account the probability of migration through the primary packaging into the food is negligible. These types of intelligent systems should not be considered as food contact materials with respect to migration testing. Nevertheless, it may be necessary to include 'intelligent substances' in a positive list for which toxicological evaluation can be kept to a minimum.

Recommendations

- Active and intelligent packaging systems manufactured from plastics only shall comply with the compositional and migration requirements (except for intentionally released substances).
- Substances intentionally released from an active releasing system shall comply with relevant requirements for food and food additives. Provisions should be made for allowance of migration values higher than the overall migration of 60 mg/kg food.
- It is proposed to draft a specific directive in which active and intelligent packaging systems are regulated. For regulation of composite materials reference to existing national regulations with regard to the base packaging materials and separate listing of the active and intelligent ingredients seems the best solution for the time being.
- Active and intelligent packaging systems should be accompanied with a declaration of compliance provided the provisions proposed have been realized.
- It will remain very difficult and laborious for enforcement laboratories to prove violation of Article 2 of Directive 89/109/EEC for complex systems. For manufacturers it may be difficult to demonstrate compliance with the rules, as they are usually not aware of the composition of all parts of the final article. A proper certification system may provide a better guarantee of the safety of the packaging system. Proper rules and guidelines, as well as the appointment of recognized certification laboratories would be required for that purpose. The scheme given in Fig. 22.2 could be a starting point for drafting a certification procedure.

22.5.4 Basic rules for migration tests

At the EU level, rules for testing plastic food contact materials are given in 82/711/EEC[10] as amended by 93/8/EEC[11] and 97/48/EEC.[12] Directive 85/572/EEC[13] provides a list of simulants that could replace real foodstuffs in migration testing. Simulants prescribed for compliance testing are water, 3% acetic acid, 10% ethanol or olive oil. In some cases olive oil may be replaced with the substitute food simulants 95% ethanol and iso-octane. In Directive 85/572/EEC it is recognized that a fat simulant may be a stronger extractive than the food. Depending on the food and its fat content reduction factors are included in the list. This means that the migration value obtained with a fat simulant should be divided by the value indicated for that particular food. The reduction factors vary from 2 to 5.

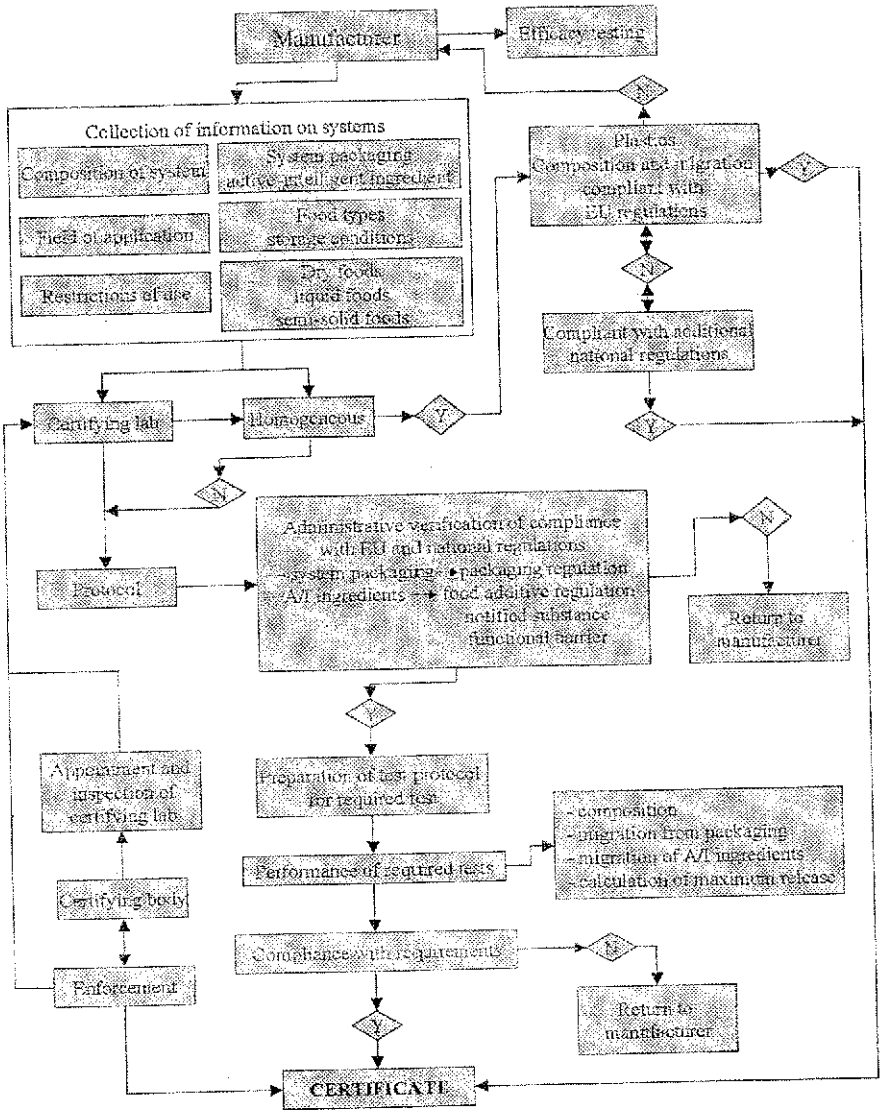

Fig. 22.2 Scheme for certification procedure.

In Directive 97/48/EC detailed conditions of time and temperature are given to demonstrate compliance with the limits set in Directive 2002/72/EC. The test conditions to be applied shall represent the worst foreseeable conditions of use in case of contact with foodstuffs. Food contact materials and articles should be accompanied with a statement indicating the restrictions of use, if any, with respect to the types of food and the maximum contact conditions of time and temperature, according to Article 6 of Directive 89/109/EEC.

Directive 97/48/EC explicitly mentions that, if the food contact material under specified contact conditions shows physical or other changes that do not occur under conditions of use, the migration test shall be carried out under the worst foreseeable contact conditions of use in which these physical or other changes do not take place. This article allows for the use of specially developed testing protocols depending on the problems encountered in the standardized testing protocols. However, the test protocols are applicable only to materials made of plastic. This means that materials composed of one or more layers not made of plastic are not covered by the EU regulation. At a national level, for example in the Netherlands, the testing protocols are used for most types of food contact materials. Detailed methods in which the requirements of these directives are taken into account have been drafted and validated by the European Standardisation Committee (CEN) in EN 1186 and EN 13130.

Relevance to A&I packaging systems

The appearance (size and shape) and the composition of active and intelligent packaging systems depend on their application. Systems used to wrap the food and made of plastics solely can be examined according to the requirements of Directive 82/711/EEC. If such a system intentionally releases substances to the food, then technically the system can be examined according to the requirements of Directive 82/711/EEC, but it may exceed the overall migration limit without endangering human health, changing the composition of the food in an unacceptable way or deteriorating sensory properties. Therefore these systems would require a special approach in interpretating migration values.

Most active and intelligent packaging systems are composed of various (non-plastic) materials. In principle, these materials are excluded from EU regulations. However, at a national level the same testing protocols are applied to most other non-plastic food contact materials. In contrast to conventional packaging materials and articles, active and intelligent packaging systems have often a very limited surface area compared to the food in contact with them. Many of these systems are not intentionally in contact with the food but only by accident. For example, a sachet with an oxygen absorber may not be in contact with the food at all at the stage of packing. During transport or handling in a retail shop the food may make contact with the absorber, but only a relatively small area of the food will be in contact with the absorber sachet. Nevertheless, migration may occur and migration testing is required to guarantee food safety. The test conditions of time and temperature can be selected from Directive 82/711/EEC, and the appropriate simulants from Directive 85/572/EEC. For active and intelligent packaging systems in contact with dry foodstuffs (without free fat on the surface) no migration tests with simulants are prescribed. If necessary, the specific migration of substances should be measured in the food itself.

Systems in contact with aqueous or fatty foods require testing with simulants. In principle, the protocols prescribe that food contact materials are brought into contact with a food simulant. This can be achieved by total immersion or by one-sided contact of the material with the food simulant. One-sided contact of plastic