22

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

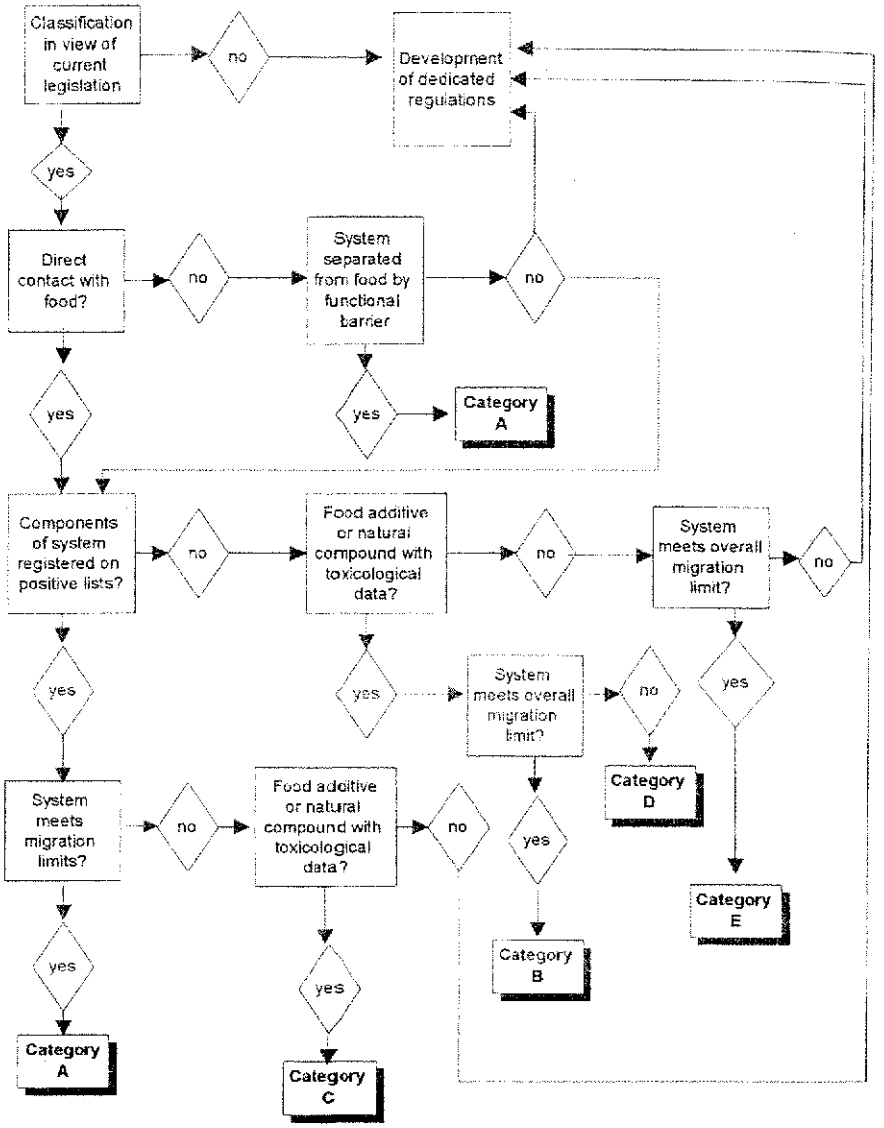

Fig. 22.1 Classification of active and intelligent food-packaging systems in view of current legislation. For a description of categories A–E, see the text (reproduced with permission from Food Additives and Contaminants, July 2002. http:/www.tandf.co.uk).

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.

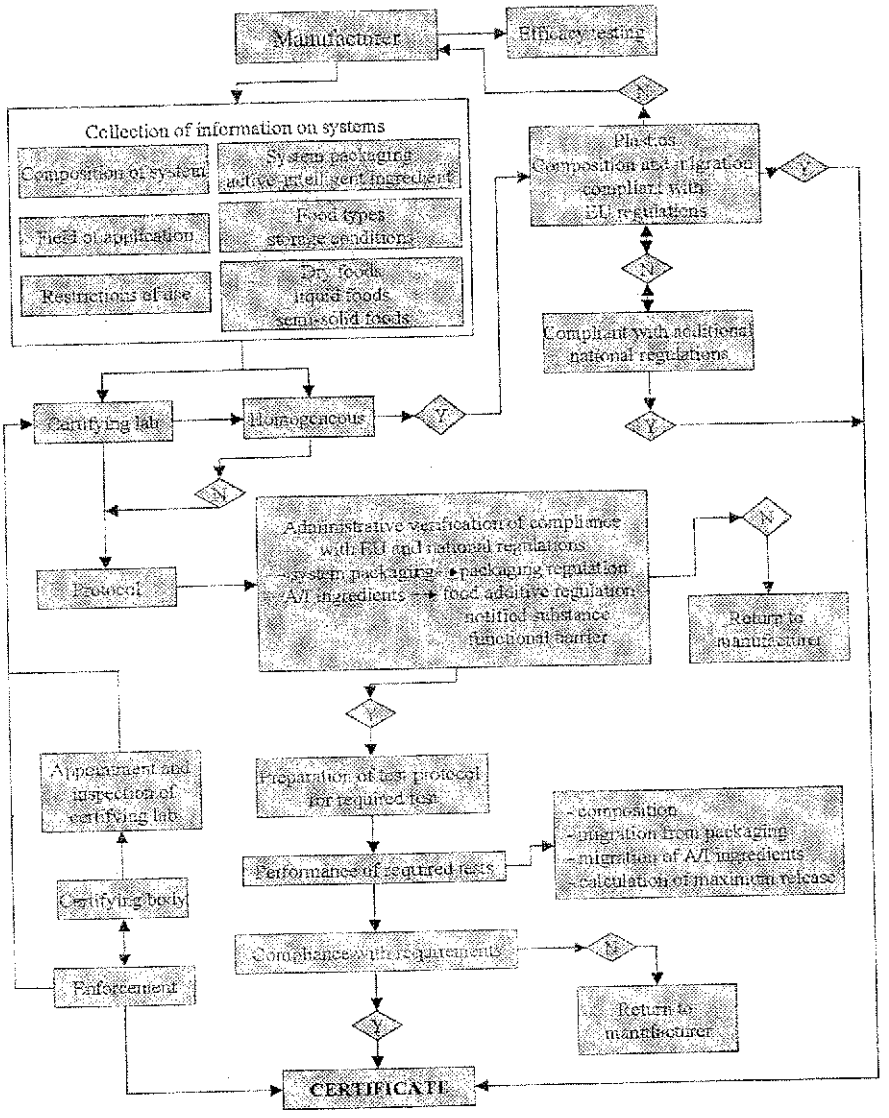

Fig. 22.2 Scheme for certification procedure.

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

materials is achievable by filling an article such as a bottle or by using a migration cell for one-sided contact. Due to the construction of many active and intelligent packaging systems this approach is not feasible, and only submersion of the article is an option. The conditions of contact and, as a consequence, the migration of substances during submersion in food simulant may deviate severely from the conditions of contact occurring under real conditions of contact. For example, the conditions of contact of a small oxygen absorber with roasted nuts are not comparable to submersion in a fat simulant, not even when the allowed reduction factor is applied. When submersing the oxygen absorber in oil the whole article is soaked with oil, which does not happen when it is in contact with nuts. Comparable situations were observed when using systems in contact with meat, for which Directive 85/572/EEC requires testing with water and oil. The tests with water and, in case of processed meat products, with 3% acetic acid by total immersion results in excessive migration of iron ions into the food simulant. After the migration period the food simulant is usually brown-coloured by iron oxide. This phenomenon does not occur with foodstuffs; otherwise, the food contaminated with brown spots would not be acceptable from a sensory point of view.

In the case of moisture absorbers, submersion of the absorber leads to contact conditions significantly different from those occurring in contact with food under real conditions as well. Active and intelligent packaging systems are in contact with the foodstuff under different conditions from conventional packaging materials. In addition, the composition (multi-layer) of the system, as well as the presence of an active ingredient, are reasons for high migration when testing under conventional conditions. Therefore, there is a need for extending the existing test protocols with so-called dedicated test methods. Within the Actipak project some experiments with dedicated tests have been performed. Oxygen-absorbing labels were tested by sandwiching the label between layers of filter paper immersed in iso-octane as the fatty food simulant. After the migration period the paper was extracted and the overall migration was determined. Migration from a paper fibre-based moisture absorber was determined with a block of agar. The agar immobilizes the water in a comparable way as water bound in meat, for example. To demonstrate potential migration the absorber was first partly saturated with water containing a fluorescent label. After the contact period the migration of the fluorescent label was measured. This test could be useful to demonstrate whether or not migration may occur. Similar tests were performed with a moisture regulator based on the hygroscopic properties of sugar solutions. Migration of iron and sodium chloride from an oxygen absorber in real food, food simulants and alternative simulants has been determined as well. The results are very promising, but need further standardization and validation.

Intelligent systems placed on the outside of the primary packaging may form a separate group. These intelligent systems are connected to the packaging material by means of an adhesive. Many intelligent systems are composed of plastic material that contains the intelligent ingredients as one of the layers of

the system or in a plastic sachet. There is no direct contact with the food. In addition, the shelf-life of foods with an intelligent system on the outside is relatively short. Even if a polyolefin is used for the primary packaging the lag time will prevent any migration. There is no need yet to require migration testing of intelligent systems connected to the outside of the primary packaging.

Recommendations

- Active and intelligent packaging systems composed of only plastic shall be tested according to Directives 82/711/EEC and 85/572/EEC.
- Substances intended to be released from an active system could be quantified by migration testing or by determination of the total amount present, while assuming that the total amount of substance present in the active system will be released to the packed food.
- The annex of Directive 97/48/EC should be extended to allow testing with foodstuffs too.
- Article 1 (4) of Directive 82/711/EEC should be amended to allow application of the provisions of the Directive to active and intelligent packaging systems not composed of plastics only.
- Intelligent systems placed on the outside of the primary packaging should be excluded from migration testing. Clause 4 of Chapter II of the Annex of Directive 97/48/EEC should be extended for that purpose.
- An additional Chapter V in the Annex of Directive 97/48/EC should be inserted to allow for dedicated test protocols for some types of active and intelligent packaging systems.
- Dedicated test protocols need further development and standardization.

22.5.5 Other directives on food contact materials

Other specific directives concerning food contact materials have been published. However, these directives do not influence the use of active and intelligent packaging systems and are hence not discussed here in detail. For the sake of completeness, these directives are listed below.

93/10/EEC[14] regenerated cellulose film
93/111/EC[15] 1st amendment to Directive 93/10/EEC
84/500/EEC[16] ceramic articles intended to come into contact with foodstuffs
2002/16/EC[17] use of certain epoxy derivatives

22.6 Food additives

The requirements for food additives are formulated in general terms in Framework Directive 89/107/EEC. Specific directives have been published on colours, sweeteners and food additives other than colours and sweeteners.

22.6.1 Framework Directive 89/107/EEC[18] as amended by Directive 94/34/EEC[19]

Directive 89/107/EEC specifies the definition for food additives and the scope of the directive. In simple terms, it states that food additives are not food ingredients or characteristic ingredients. Food additives are intentionally added to attain a technological effect during manufacturing, storage and distribution of the food. Various categories of food additives have been identified, each with its typical properties. Food additives are allowed only if there is a technological need, if there is no hazard to human health and if they do not mislead the consumer. Consumers should be informed about the presence of additives in foodstuffs by means of proper labelling of the food or the food additives. At a national level specific requirements on listing the ingredients as well as their traceability may exist.

Relevance to active and intelligent packaging systems

The directive on food additives is relevant only to systems that intentionally release substances into the food. The substance intentionally released from an active system should in the first place be an allowed food additive covered by one of the categories listed in Annex I of Directive 89/107/EEC. In addition, there should be a technological need that cannot be met by other means. Validity of this clause may be difficult to demonstrate but active systems fulfil a technological function in the food when food is already packed. In addition, the requirement to add the lowest level possible to achieve a desired effect may support the use of active systems. Active systems usually will be active at the surface of the packed food, whereas a food additive is often mixed into the food. As a result, the total amount of a substance may be significantly reduced when using an active system.

Foods may contain a substance that is also released from an active packaging system. In those cases, the final concentration in the food should be taken for a proper judgement of compliance with regulatory requirements. The food packer will carry that responsibility in first instance. The proper labelling of the active releasing system concerning the maximum amount of substance released from an active system avoids the possibility of that maximum limit being exceeded. Active releasing systems may release the food additive via the headspace of the packed food to obtain a distribution as uniform as possible. In other cases the transfer of substances may be caused by intense contact with the active system. In both cases the concentration at the surface may be higher than the maximum allowed concentration. However, measured on the basis of the bulk of the food the amount of food additive should be significantly below the allowed concentration limit. Taking into account that the whole bulk of the packed food is consumed this should not be a problem. In analysis of the foodstuff a proper homogenization of the food should be ensured.

Recommendations

- Directive 89/107/EEC does not form any hurdle to the use of active and

intelligent packaging systems. The substances released from active packaging systems shall comply with the requirements of this directive.
- Foods in contact with a releasing system should be homogenized before analyzing the food on the total amount of the relevant food additive.

22.6.2 Specific directives on colours, sweeteners and food additives other than colours and sweeteners

In addition to the Framework directive, specific directives on food additives have been published. Directive 95/2/EC[20] (last amended by 2001/5/EC[21]) provides a glossary of the various categories of food additives covered by the directive. Also substances not included in the directive are indicated, for example substances for the treatment of drinking water. The directive is based on the positive list principle. The substances, provided with a so-called E number, are listed in five separate annexes. The annexes list substances for general use or for use in specified foods or concentrations.

A relevant issue is the packaging gases that are allowed in all foodstuffs. In this respect, the Directive defines packaging gases as gases other than air, introduced into a container before, during or after placing a foodstuff in that container.

Packaging gases provided with an E number are carbon dioxide, argon, helium, nitrogen, dinitrogen oxide and oxygen. The additives are subject to purity requirements, which are laid down in specific directives. Requirements for colours used in foodstuffs are laid down in Directive 94/36/EC.[22] Colours allowed to add or restore colour in foodstuffs include colours of natural sources. In five annexes the permitted colours and the conditions of their use are laid down. The annexes include a positive list, a list of foodstuffs that may not be coloured, and colours with restricted uses.

Directive 94/35/EC[23] (as amended by Directive 96/83/EC[24]) concerns the use of sweeteners added to foodstuffs. Only the sweeteners listed may be used in the foodstuffs listed at a level fulfilling the intended purpose and shall not mislead consumers.

Relevance to active and intelligent packaging systems

The specific directives of the framework Directive 89/107/EEC are relevant only to releasing systems. The specific directives are detailed and do not allow deviations. Therefore, the releasing systems should comply with qualitative and quantitative requirements on food additives. Manufacturers and food packers should realize that a releasing system may not be generally applicable to all foodstuffs but only to specified ones. Therefore, it seems obvious that the manufacturer of releasing systems should give proper instructions and define conditions of use, although the final user or food packer has his own responsibility as well.

None of the specific directives mentions the removal of substances from the packed foodstuffs. This may be logical as the directives are dealing with

additives. The use of an oxygen absorber, which removes oxygen from the headspace of the packed food, is excluded from the directive whereas flushing with nitrogen is included. The resultant packaging gas is, however, similar. The application of gas absorbers is not covered by any directive and remains the responsibility of the food packer. As the application of oxygen absorbers is very similar to the use of packaging gases, it seems logical that labelling and food safety are handled in the same way.

Labelling of packed food

Packaging gases used for packaging certain foodstuffs should not be regarded as ingredients and therefore should not be included in the list of ingredients on the label. However, consumers should be informed of the use of such gases inasmuch as this information enables them to understand why the foodstuff they have purchased has a longer shelf-life than similar products packaged differently. Therefore, the following text should be used on the label in the national language: 'packed under a protective atmosphere', as is required for modified-atmosphere packaging

Food safety

When the atmosphere inside a package is altered, the limiting factor for shelf-life may also change. For example, in an oxygen-free atmosphere the growth of aerobic micro-organisms is inhibited, but this atmosphere may promote the growth of anaerobic micro-organisms. The limiting factor for shelf-life may then become the growth of anaerobic micro-organisms. A similar reasoning may be valid for preservative-releasing systems. Shelf-life studies should reveal the spoilage mechanism and the actual shelf-life of the food should be established.

Recommendations

- Food additives released from active packaging systems shall comply with the requirements laid down in the framework directive and its subsequent specific directives. Limits and requirements on the total quantity of additives in foods and the purity of the additives shall be obeyed. Also the limitation of addition of substances to specified foods must be taken into account.
- Oxygen absorbers should be included in the section about modified-atmosphere packaging by amending Article 1(3 r) of Directive 95/2/EC as follows:

  'packaging gases' are gases other than air, introduced into a container before, during or after placing of the foodstuff in that container, or by selective removal of oxygen after placing of the foodstuff in that container'

- Substances released into food shall be labelled according to requirements on labelling.

22.7 Food flavouring

Framework Directive 88/388/EEC[25] (as amended by 91/71/EEC[26]) concerns flavouring substances for use in or on foodstuffs to impart odour and/or taste. The flavouring substances should be obtained from materials of vegetable or animal origin or by chemical synthesis. Flavourings should not imply addition of any element or substance in a toxicologically dangerous quantity. Maximum levels for arsenic, lead, cadmium and chromium have been set. Also the content of 3,4-benzopyrene is limited in all foods. There is a short list of substances that may be used at certain maximum concentrations in foodstuffs.

Labelling requirements concerning the description, quantity, suitability for food use and traceability have been laid down. In Council regulation EC 2232/96[27] a procedure is laid down which includes the listing of all flavouring substances in use in the EU member states. The substances will be evaluated to establish their conditions of use. Commission decision 1999/217,[28] as amended by Commission decision 2000/489,[29] lists more than 2800 substances The registration is a first step to a harmonized positive list of flavouring substances. The Nordic countries have some specific rules for the use of flavourings in certain food products.[3]

Relevance to active and intelligent packaging systems

Active packaging systems releasing flavourings are by definition an attractive way of flavouring food. A flavour added to the packed foodstuff will generate an attractive or characteristic smell when consumers open the packed food. Sausage casing may be flavoured to release the smoke flavour to the sausage in order to obtain a flavour taste and to preserve the sausage. A classic example is the use of wine barrels, which are used to store the wine but at the same time release their flavour to the wine, which may be characteristic of the wine. In modern wine making wood chips may be used to obtain the same effect. Although a wine barrel is clearly an active packaging material in the definition of active packaging systems, for historical reasons and because of the natural origin, wine barrels could be excluded from classification as an active packaging material. Application of flavour-releasing systems will not be hindered by the existing regulations on flavouring, provided the rules laid down for flavouring of foodstuffs are taken into account.

Release of flavour, can however, also be used to hide some negative aspects of the foodstuff. Directive 88/388/EEC clearly indicates that flavouring must not be allowed to mislead consumers. The use of flavouring to hide spoilage is not acceptable; it would mislead consumers and may cause serious food poisoning. But, when the flavour is added in order to overwhelm an off-flavour of the food and the use of flavouring does not cause any toxic harm it may be found acceptable. Active flavour-releasing systems are also strong tools to avoid so-called scalping of flavour of packed foods. By supplementing the flavours through the packaging material this effect could be avoided.

Another category of active packaging systems that may mislead consumers are absorbers. For instance, an absorber could be used to remove the amine smell of fish and, as a consequence, consumers will be deprived of a sensory indicator for spoilage. These types of active systems are not covered by the flavouring regulations but are actually comparable to hiding effects or, in the worst case, misleading consumers.

Recommendations

- There are no fundamental objections to the use of an active system that releases flavouring substances, provided the regulations on flavouring are followed.
- Allowed total quantities of flavourings in foods shall not be exceeded.
- Flavouring to hide spoilage is not allowed.
- Flavouring to mask natural or synthetic off-flavours should be further studied. Conditions of acceptability should be drafted.
- Removal of substances is not an issue of the flavouring regulation but needs legal attention. Appropriate provisions could be included in the specific directive on active and intelligent food contact materials.

22.8 Biocides and pesticides

Biocides are substances intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means, as defined in Directive 98/8/EC.[30] Several areas are excluded from the directive. Among others, food additives subject to Directive 89/107/EEC and food contact materials subject to Directive 89/109/EEC are excluded from the biocide regulations.

22.8.1 Relevance to active and intelligent packaging systems

The biocide regulation excludes food additives and food contact materials. Thus, any substance with a biocidal effect should be listed in these regulations. Active systems intended to release a biocidally active substance into foods are limited to the use of substances allowed as food additives. All requirements and restrictions laid down in the regulations on food additives must be taken into account. Only in bulk transport is the use of biocides as well as pesticides allowed. A ship cargo space may be gassed with biocides or pesticides to protect the food. This may also be feasible with active systems of sufficient capacity. This is considered a special category of application that should comply with the rules presently valid.

Often confusion is brought about with regard to the use of biocidal substances in food contact materials. There are two reasons to add biocidal products to food contact materials. First, it may be necessary to stabilize a polymer emulsion before manufacturing the final article. This application is indispensable to allow

transport and storage of the semi-manufactured product. A second application, of increasing interest, is the addition of antimicrobial substances to protect the surface of the final article from microbial contamination. In both situations the addition of the biocide should not be considered as an active system as there is no intentional influence on the food. In both cases migration of the substance should be negligible or as low as possible; anyway, there should be no effect on the food in contact with the materials.

Recommendation
The regulation on biocides excludes food contact materials and food additives. Therefore, all applications related to biocidal substances are subject to regulations on food contact materials and food additives.

22.8.2 Pesticides

Directive 91/414/EEC[31] regulates the use of pesticides, which, in short, are active substances to protect plants and plant products against harmful organisms. Plant protection products (pesticides) are used on agricultural produce and are not added to foodstuffs as preservatives. Maximum residue levels (MRLs) for each specific pesticide in agricultural produce have been defined in the Directive, either for a group of products or for individual products.

22.8.3 Relevance to active and intelligent packaging systems

The use of pesticides is legal only if approved for a specific use or on specific agricultural produce. At the pre-harvest stage the use of active packaging is unlikely even if possible. However, some products may also be treated with pesticides at the post-harvest stage; for example, the use of certain plant growth regulators for potatoes is authorized as well as some insecticides on cereal grains. The use of these pesticides is usually a matter of bulk treatment. Protective substances on potatoes or cereal grains may or may not be volatile. Treatment with non-volatile agents is unlikely as it will not be effective on the bulk of food. The protection of potatoes with volatile substances may be feasible but due to the batch treatment this is unlikely. No such applications are currently in use or under development. When active systems are developed then they should comply with the rules on treatment of food products. Impregnation with biphenyl of paper used for packaging citrus fruits has been known for many years. However, in this application biphenyl is regulated as a food additive.

Recommendation
When active systems are developed, they shall comply with the regulation on pesticides.

22.9 Food hygiene

The aim of Council Directive 93/43/EEC[32] on the hygiene of foodstuffs is to control all activities critical to food safety, and thus it covers all aspects affecting hygienic production, storage, packaging and distribution of foodstuffs, in order to ensure the safety and wholesomeness of foodstuffs. The Directive aims at establishing uniform minimum requirements for food production to ensure that only safe food is retailed. Regulations on veterinary products, such as Directive 92/5/EEC[33] for meat products, contain more detailed requirements (e.g. approval of establishment, stricter temperature conditions, official controls) for the production of some products of animal origin. Special provisions for the hygiene of quick-frozen foodstuffs are given in Council Directive 89/108/EEC[34] to protect them from microbial or other external contamination and from drying.

To achieve safe food the directive requires protection of the food within the food production chain against any contamination that renders the food unfit for consumption. Foods supporting the growth of pathogenic micro-organisms or the formation of toxins should be kept at temperatures that will not endanger health. Principles of HACCP (hazard analysis of critical control points) as given by the FAO/WHO Codex Alimentarius Commission[35] should be followed. Food packaging materials are not directly covered by the EC Directive, but hygienic conditions of the packaging materials will be a prerequisite in hygienic food production. Neither the microbiological criteria for foodstuffs nor the temperature requirements have been harmonized in the European Union. Various time-temperature requirements can therefore be found for certain food categories in different countries.[36] Where no legislation exists, the manufacturer may freely choose the best storage temperature for the product provided the product is safe for consumption.

Although legislative requirements and recommendations for temperature control during manufacturing, heating, cooling and chilled storage are abundant, there are no rules in food legislation on how long food quality should remain acceptable. Directive 2000/13/EC[37] on labelling requires pre-packed foods to bear a date of minimum durability or, for highly perishable foods, a 'use by' date. It is the manufacturer's responsibility to determine the shelf-life of the product, taking into account storage conditions, and to ensure that the product is safe throughout its assigned shelf-life. The shelf-life of foods depends on the specific properties of the food product and the environmental conditions in which the food is treated and stored. In particular, the shelf-life of microbiologically sensitive foodstuffs will depend on storage conditions of time and temperature.

22.9.1 Relevance to active and intelligent packaging systems

The Food Hygiene Directive requires that all measures be taken to ensure the safety and wholesomeness of foodstuffs during production, transport, storage and offering for sale or supply to the consumer. The use of active systems may

be helpful to maintain the quality of the food and to extend its shelf-life. Intelligent systems could provide reliable information on the conditions of the food by showing, for instance, the time and temperature conditions during the life cycle of the food, or by detecting gases generated by micro-organisms.

The use of an oxygen absorber will suppress the growth of certain micro-organisms. The use of preservative-releasing systems will have a similar final effect. Foodstuffs will not only have a longer shelf-life but will also be safer at the time of consumption. The use of moisture absorbers, for example for packaged meat, has in the first instance a visual benefit as the meat juice is absorbed by the absorption pad. If, however, such a pad is treated with a selected mixture of spices, then microbial deterioration will be slowed down resulting in a longer shelf-life and safer product.

It is required today to print on packaged food the 'use by' date. Usually the 'use by' date is established on the basis of experience. For products with a long shelf-life this does not cause any problem as the storage time and temperature conditions are not very critical. For products with a long shelf-life chemical deterioration is usually the limiting factor, whereas for foods with a relatively short shelf-life microbiological conditions are often the limiting factor. Food packers may extend the safety margin to allow of some 'misuse' during transport by consumers from the retailer to their homes, or incorrect temperature settings during display. Use of a time/temperature indicator could indicate the safety of the food by indicating that the allowable storage conditions of time and temperature have not been exceeded. These time/temperature indicators could prevent unnecessary waste of food due to the elapse of the 'use by' date, which of itself is no guarantee that the food is fit for consumption. The indicator will inform consumers whether the product is still suitable for consumption. These indicators could replace the requirements of printing 'use by' dates when it is demonstrated that they are reliable and when the consumer is familiar with the use of the indicators. However, most time/temperature indicators are not capable of giving proper information on the period still to go before the 'use by' date is passed. This could be overcome by printing the production date or date of packing on the packed food instead of a 'use by' date in addition to an indication of the shelf-life. This approach would require, of course, a range of indicators with variable 'response times' to allow the use of a proper indicator.

Modified-atmosphere packaging with packaging gases is a frequently used method to preserve foods. However, if the gas-tightness of the package fails, the protective atmosphere will change and the food may become unfit for consumption. This is very difficult to observe both for the manufacturer and for consumers. Insertion of an indicator that detects, for example, oxygen will provide information not available without the indicator. Similar indicators can be inserted to detect the generation of microbial respiratory gases. The Food Hygiene Directive requires 'all measures necessary to ensure the safety and wholesomeness of foodstuffs'. The use of both active and intelligent packaging systems is a new means of meeting this requirement. Actually, the requirements of the hygiene directives strongly support the use of active and intelligent systems.

Recommendation
Allowance should be made in the Food Hygiene Directive to replace the 'use by' date with dedicated time temperature indicators.

22.10 Food labelling, weight and volume control

Labelling of foodstuffs is meant to give consumers information on the composition of the food and to protect them. In Directive 2000/13/EC requirements for labelling of foodstuffs to be delivered to the ultimate consumer are laid down. Labelling of the foodstuff should not mislead the ultimate consumer. Detailed but generally applicable requirements have been formulated as to the information to be provided. Major issues are: name, list and quantities of ingredients, shelf-life, name and address of the manufacturer, instructions for use, etc. All ingredients should be listed in descending order of quantity.

Food additives shall be designed by their category name followed by their specified name or EC number, for example 'Emulsifier E 322'. Also requirements on the minimum durability of the foodstuff should be printed by using the wording 'best before ...' or 'use by ...' depending on the perishable nature of the foodstuff. Directive 89/109/EEC lists requirements on labelling of packaging materials. This concerns, however, not the final product but the packaging material when it is not in contact with the food. In that case the packaging material should be accompanied with instructions for use such as suitability for various types of foodstuffs and maximum temperature range. In addition, it should be possible to trace back the packaging material to the manufacturer in case of a calamity.

22.10.1 Relevance to active and intelligent packaging systems

Directive 2000/13/EC requires listing of food additives used in the manufacture or preparation of foods and still present in the finished product. It may be questionable whether an additive released from the packaging material is added during manufacturing or preparation, but no doubt it will be present in the final product. Therefore, any substance intentionally released into the food while being packed should be listed according to the rules of Directive 2000/13/EC. Requirements on total quantities should be respected, irrespective of the stage at which the substance becomes part of the foodstuff. Intelligent systems could supplement the information presently given to the consumer. It is conceivable that labelling requirements could be changed due to the information given by intelligent systems. For example, 'use by' dates could be replaced by information obtained from a time-temperature indicator. However, the introduction of intelligent systems and consumer education regarding interpretation will be needed before making any changes to labelling requirements in this respect.

Active and intelligent packaging systems may be incorporated in the packaging material of the foodstuff. They can also be packed with the food in

the form of a sachet, box or label. Consumers should be made aware that the object included in or on the packed food is not a part of that food. Sachets with a powder could easily be confused with ingredients like salt or pepper. Great care should be taken to prevent the consumers eating it. Labelling only by text seems not sufficient. Consumers who cannot read must be protected as well. Therefore, the introduction of a harmonized universal symbol, which indicates that the object is not part of the foodstuff, seems appropriate. According to labelling Directive 2000/13/EC, the ultimate consumer should be informed properly. Therefore, also information on the function of the inedible active or intelligent packaging system, should be printed.

Usually, active and intelligent packaging systems will not be available to the consumer as such. They will be purchased by food manufacturers and food packers. The manufacturers should also be informed about the range of applications and restrictions of use as well as about the quantity of additive that may be released from an active system. This could be achieved by means of documents attached to a batch of articles.

Recommendations

- Labelling of foods shall be in compliance with Directive 2000/13/EC. Substances released from a system should be considered a food additive added during manufacturing or preparation of the food.
- Requirements on labelling, at the retail stage, should be formulated with the aim to inform the consumer about:
  - the presence of a non-food component
  - the function of the system
  - inedibility of the system by means of written text and a pictogram
  - any possible risk upon digestion of a system.

  These requirements could be added to the directive on labelling, but it may be more appropriate to add them to the specific directive on active and intelligent food contact materials.
- At the wholesale stage, active and intelligent packaging systems should be accompanied by a certificate of compliance with regulations of food contact materials.
- Instructions on conditions and restrictions of use should be given at the wholesale stage.

22.10.2 Weight and volume control

Several EU directives deal with the weight and volume control of pre-packaged food. Directive 75/106/EEC [38] and Directive 76/211/EC[39] relate to pre-packages made up by volume and weight respectively. The pre-packages must bear an indication of the product weight or volume, known as 'nominal weight' or 'nominal volume' which they are required to contain.

22.10.3 Relevance to active and intelligent packaging systems

Active systems may influence the weight or volume of the foodstuffs. In the case of emitters of food additives (preservatives, flavouring compounds, etc.) the migration of these compounds will have a negligible effect on the weight or volume of the food. Lightweight foods, such as chips and dried herbs, may be exceptions. Moisture absorbers, such as an absorbing pad for meat drip, usually have a noticeable effect on the net weight of meat. The aim of the Directives on weight and volume control is to ensure that consumers are correctly informed on the net quantity of the food. If the active system influences the weight or volume, this must be taken into account in the declared weight or volume.

Recommendation

Active packaging systems with absorbing properties should take into account the loss of weight due to the absorber.

22.11 Product safety and waste

Directive 2001/95/EC[40] concerns general product safety. The general product safety directive dictates that all products placed on the market shall be safe. 'Safe products' mean that under normal or reasonably foreseeable conditions of use the product does not present any risk or only the minimal risks compatible with the product's use. In the judgement of safety aspects the characteristics of the product, presentation, labelling instructions and the category of consumers, in particular children, should be considered. Manufacturers are obliged to provide the relevant information to the final consumer.

22.11.1 Relevance to active and intelligent packaging systems

The general product safety directive applies to active and intelligent systems. The active or intelligent system may never endanger food safety or consumer health. To comply with safety a number of issues have to be considered before bringing systems on the market.

22.11.2 Labelling of active and intelligent systems

Several active and intelligent systems are present inside the primary packaging, such as sachets, cups and pads. It has to be made clear that these systems are not suitable for consumption. There should be no confusion with sachets or cups that contain, for example, herbs, salt or butter, which are intended to be consumed with the packaged food. Therefore, on the active or intelligent system a well legible, indelible warning has to be placed in at least the national language that the active or intelligent system is not to be consumed, for example 'DO NOT EAT'.

Functionally dyslexic people and those not able to read the national language should be able to understand the warning 'DO NOT EAT' by means of a symbol

Fig. 22.3 Proposed symbol to warn consumers not to eat the system.

printed on the label. This symbol has to express that the content of the active or intelligent system is not suitable for consumption. Harmonization of the wordings and the symbol would enhance the understanding of the wording and symbol in a short period of time, whereas the use of different indications would confuse the consumer. Within the Actipak project a symbol is proposed which is shown in Fig. 22.3. Possibly better designs could be developed, but the main issue is that only one symbol should be adopted for harmonization.

22.11.3 Size and shape of active or intelligent systems

A recommendation has been issued to member states to take action to prevent consumption of the non-food article. In this respect children, mentally disabled patients and elderly people are considered high-risk groups. It is therefore advisable that the non-food article is so large that adults cannot swallow it. For toys[41] the minimum size is determined on the basis of a defined cylinder, resulting in a size of 3.17 cm. For adults the minimum size should be increased to 5 cm. In addition, the non-food article should have a morphology distinguishing it from the packaged food. Another possibility is to thoroughly attach the active or intelligent system to the packaging.

Content of active and intelligent system

If, for any reason, the active or intelligent system releases its chemicals, no acute danger to the consumer may occur. Therefore, active and intelligent compounds present in sachets, cups or pads used in consumer packaging should not be seriously irritating, corrosive, harmful or toxic. Furthermore, these compounds shall not be carcinogenic. Directive 67/548/EEC[42] can be used to classify dangerous substances. Some active or intelligent systems consist of a film that incorporates the active compound. In these cases the Scientific Committee on Food has to assess their toxicity and migration behaviour and set limits accordingly.

22.11.4 Food imitation directive

Products referred to in the Food Imitation Directive 87/357/EEC[43] are those which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size such that it is likely that consumers, especially children, will confuse them with foodstuffs and consequently place them in their mouths, or suck or ingest them, which might have serious effects.

Member states are obliged to take all measures necessary to prohibit the marketing, import and either manufacture or export of unsafe products.

22.11.5 Retail versus wholesale

Active or intelligent packaging systems can also be used in wholesale food applications, for example, during transport of wholesale packaged foodstuffs. These active or intelligent systems will not reach consumers. The final users are then professional employees, not the risk groups of children, elderly people and mentally disabled persons. Therefore, active and intelligent systems used in wholesale that are not intended to reach consumers do not have to comply with the previously described safety aspects regarding the size and content, or the food imitation directive.

Recommendations

- Measures should be taken to harmonize the text and symbol to be printed on active and intelligent packaging systems.
- Requirements on size and shape as laid down in toys regulations should be made applicable to movable objects packaged with foodstuffs.
- Quantities of substances that could have *serious health* or *lethal* effects should not be allowed.
- Directive 87/357/EEC on food imitation may be applicable to active and intelligent packaging systems depending on the appearance of the system. Manufacturers should consider this directive, in particular in the developmental phase of their system.

22.11.6 Waste

Waste Directive 94/62/EC[44] describes measures aiming at preventing the production of packaging waste. It additionally aims at reusing, recycling or recovering packaging waste to reduce the final disposal of packaging waste. The directive covers all packaging placed on the market regardless of the material used. The directive is applicable to all types of packaging waste. Member states in communication with stakeholders are encouraged to promote reuse of packaging materials. Identification codes should facilitate collection, reuse and recycling. Restrictions as to the levels of lead, cadmium, mercury and hexavalent chromium must be reduced in time. The directive mentions the recycling processes actually available. The directive also assumes that materials can be reused only when appropriate. Packaging use shall be reduced to a minimum.

Relevance to active and intelligent packaging systems

In environmental issues it is often necessary to perform a life cycle analysis. Only in that way is it possible to establish whether the use of a certain type of

packaging material is the most appropriate. Addition of an active or intelligent packaging system may require an additional amount of packaging material resulting in more waste. However, if by virtue of a longer shelf-life of the packed food the waste of packaging material and food is reduced, the scale could easily be turned in favour of the use of active or intelligent packaging systems. Recovery of food contact materials, with the exception of paper, glass and metal, is limited. In recycling of plastics only recycled polyethylene terephthalate is commercially applied. For most other polymers recycling of food contact plastics into new articles is still on a modest scale. Collection, sorting, cleaning and processing is cumbersome, as the directives on plastics require that the material shall be safe and comply with the positive list. This means that recycling of complex mixtures like active and intelligent packaging systems is currently not an issue.

The presence of various chemicals, present only in relatively small quantities, may meet objections upon incineration but if the substances are of organic nature they will be incinerated. Oxygen absorbers containing iron may produce some additional slag. In general, no problems are manifesting themselves now but developers of active and intelligent packaging systems should take into account possible environmental consequences.

Recommendation

- Manufacturers should consider the use of active and intelligent packaging systems in view of environmental issues.

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