



Review of COM 689 – European Commission proposal for a regulation of the European Parliament and of the Council on materials and articles intended to come into contact with food

Prepared for the European Parliament Committee on Environment, Public Health and Consumer Policy

INTRODUCTION

This review has been prepared under the terms of a contract between EASAC and the Committee on Environment, Public Health and Consumer Policy, for the provision of scientific advice in the area of Environment, Public Health and Food Safety. The task assigned to EASAC is to give expert, independent comments on the scientific aspects of the Commission document; it is not our intention to deal with the economic or internal market aspects.

EASAC identified four independent experts through the network of the member Academies of EASAC to review the Commission document COM 689, briefing them about the task and collating their individual reviews into a single document. The process of collation is intended to produce a coherent, comprehensive and authoritative review while respecting any divergence of opinion among the reviewers. The experts whose reviews are collated in this Report come from Finland, Italy, UK and Eire and their expertise covers food technology, packaging technology, nutrition and public health.

The names of the individual reviewers remain confidential and, in keeping with normal EASAC practice, the reviewers were not paid for their reviews. All reviewers were asked to disclose any interests that might be judged to affect their ability to review the Commission document impartially. None disclosed any such interests.

SUMMARY

In this proposal, the European Commission recommends a Regulation to cover novel packaging materials, arising from advances in science and technology, designed to maintain or improve the condition of food and prolong its shelf life.

The EASAC reviewers advise that the proposal addresses some important issues and that this is an active area of technology development. One concern is that some of the potential applications (for example, flavour-absorbing active packaging) may be contentious and the proposal, generally, would be improved by a more detailed discussion of safety issues and a more balanced consideration of the innovation issues for consumer safety and industry benefit.

The proposal would also be strengthened by better exemplification of the scientific potential in the explanatory memorandum and by a more thorough consideration of specific issues for environmental impact, testing procedures and facilities, and labelling.

BACKGROUND

The European Commission notes that Directive 89/109/EEC provided the basis for the assurance of a high level of protection of human health and of consumers' interests in relation to materials and articles intended to come into contact with food, whilst also ensuring the effective functioning of the internal market. That Framework Directive established general principles applicable to all materials in contact with food:

'Inertness' of the materials and 'purity of the food', that is migration of substances from the material or articles into the food shall not endanger human health and shall not bring an unacceptable change in the composition of the food or its organoleptic characteristics;
'Positive labelling' for materials and articles intended to come into contact with food.

However, technological progress has led to the recent development of new types of food packaging. The so-called 'active' food contact materials and articles have been designed to maintain or improve the condition of the food and prolong its shelf life. Other new packaging applications known as 'intelligent' food contact materials and articles are used to give information about the condition of the food. It is currently unclear if these types of packaging are covered by national or Community legislation. The new proposal is therefore intended to clarify that these two types of materials and articles in contact with food are covered by the Regulation, and sets basic rules for their use. It also foresees the possibility of drafting specific implementing measures for them.

In the accompanying Press Release (17 November 2003), the Commission emphasises the need to amend EU law so as to develop a more modern approach to materials that come into contact with food, provided such packaging complies with the principles of EU food safety law. Examples are given of recent technological developments whereby active packaging materials interact

with food so as to reduce oxygen levels (for example, to inhibit mould growth) or add flavourings or preservatives. Intelligent packaging could change colour to inform the consumer how fresh the food is and to show whether the food has spoiled because of a change in temperature during storage or a leak in the packaging.

The new obligations for manufacturers will include application for the authorisation of a substance to the national competent authority of a Member State in the first instance, and informing the Authority about new information that may influence the evaluation of the safety in the use of an authorised substance. Little economic impact is foreseen insofar as the current system already requires evaluation and labelling of substances used for the manufacture of food contact materials. Thus, the policy objectives of the proposal include the free movement of materials and articles intended to come into contact with food, taking into account technological developments and securing a high level of protection of human health and the interests of the consumer. In addition, there are objectives of improved traceability of materials and transparency of the authorisation process and better enforceability of the rules through the establishment of Community and national Reference Laboratories.

Active packaging approaches are already on the market in the USA, Japan and Australia. A recent publication from the European Commission Joint Research Centre at Ispra ('Active packaging for SMEs: uses, legislative aspects and science') emphasises that development and application of the concepts in Europe require continuing research into its safety, effectiveness, economic and environmental impact, as well as unknown consumer acceptance.

SCOPE OF REGULATION

The EASAC expert reviewers agreed in noting that science and technology developments over the last 20 years have brought new opportunities and new needs for regulation of packaging materials. While technological progress in the area of food packaging has produced a range of 'active' and 'intelligent' food contact materials and articles, their introduction into the EU is difficult currently because they are not clearly covered under any specific EU Regulation. The modification of Directive 89/109/EEC so as to cover active and intelligent packaging owes much to a recent (1999-2001) European initiative, 'Evaluating safety, effectiveness, economic-environmental impact and consumer acceptance of active and intelligent packaging' (ACTIPAK), which extensively investigated the effectiveness and reliability of the main types of packaging concepts, drawing substantially positive conclusions and forming the basis of the legal framework provided by the proposed Regulation. The Commission's proposal involves changing the Directive into a Regulation, which will be more flexible for provisions such as positive lists. The changes toward a more flexible authorisation procedure and new instruments

for implementing provisions should permit a more rapid and effective response to innovative developments. Attention to detail in the Commission's proposal (and the additional critical points made below) is important if the Regulation is to be proportionate to the significance of the technological changes in this area, with respect to economic issues, innovation and practical implications.

While there is significant scientific background in this area, building on a well established evidence base from chemistry and physics (a list of key references provided by the EASAC reviewers is available for consultation), it should be emphasised that the concepts developed are quite novel compared with the traditional demands for food packaging materials – protecting food against physical, biological and chemicals risk, customarily requiring maximum inertness and minimum food contamination. Most of the reviewers felt that the science base in this area is not controversial and that the proposal is comprehensive, broadly sensible and logical. If appropriately overseen, there is the prospect that an objective and scientifically based approach to the control of migration and chemical contamination can succeed – and the scientific and industry organisations who contributed to the proposal and were involved in its preliminary assessment are aware of the scientific implications of the state of the art in this area. Reviewers observed that the proposal would benefit from more detail and specific examples of the expected scientific advances and technological implications.

Some of the EASAC reviewers, however, emphasised that benefits to the industry sector should not be considered first and foremost; rather the starting point in this Regulation (as in others) is to protect consumer health and interests. In this context, noting that active and intelligent packaging has been on other international markets for some years, reviewers advised that it was important to confirm that the experience and relevant regulations in those other countries had been taken into account by the Commission while preparing this proposal.

SPECIFIC TECHNICAL ISSUES

The proposal is of a rather general nature and the reviewers focused on a range of specific issues that require further critical evaluation with regard to safety.

(i) Active food packaging materials. The materials are designed to release active components into the food or in the microclimate around it, or to absorb deleterious substances from the food or the headspace around the food (usually gases such as oxygen, carbon dioxide, ethylene). The released components could actually be regarded as food additives and, therefore, covered by food additives regulation. The example of oxygen is particularly important. One reviewer noted that when oxygen is absorbed from the package headspace by oxygen scavengers, there is a danger with high water activity foods that anaerobic microbes (such as *Clostridium botulinum*) could begin to grow, if the storage temperature is not sufficiently low. As the results could be fatal to the customer, there needs to be more discussion (and, perhaps, warning on the food label) of the important safety aspects related to active packaging.

(ii) Inedibles in food packaging. Oxygen/carbon dioxide absorbents are often used in the form of small scavenger pouches inside the package. They can be regarded as inedibles in food packaging, which might cause a health danger to small children who think they are edible candies. One reviewer cites the example of incidents in Japan, where small children have accidentally eaten oxygen scavengers, usually iron powder, enclosed in a small pouch inside the food package. If scavenger pouches are to be used, then there will need to be a clear warning sign on the label for parents – this safety issue was also not discussed in the proposal. Alternatively, to avoid this safety problem, the absorbent system could be built immobile in the packaging material itself, or possibly in the label tag.

(iii) Flavour-releasing active packaging. One reviewer advised particular caution in this application, which gives the food producer or packager a possibility to mislead (and, even, cheat) consumers about the real quality of the food produced – by releasing into the headspace of the package flavourings that cover the spoiled flavour of deteriorated foodstuff. This reviewer recommends that such applications should not be permitted.

(iv) Flavour-absorbing active packaging. Several reviewers raised a concern that these might also be used to mislead consumers – active packaging materials that are able to absorb unpleasant volatile substances from the headspace and product itself (aldehydes, amines, acids and non-specific flavour scavengers). For example, when the packaging absorbs aldehydes formed in the auto-oxidation of unsaturated fatty acids of cereal or bakery products, the consumer may think that the product is still of high quality although it is actually highly auto-oxidised and may even be dangerous to

health. Similarly, with fish packaging, where amines formed in the spoilage process are absorbed by active flavour absorbing packaging. Traditionally, such flavours are perceived by consumers as sensorial indices of spoilage, and consumers could be misled if signs of spoilage are manipulated – such practices may be judged both unethical and dangerous. The consumers organisation (BEUC) has already expressed its concerns for this potential risk.

One reviewer notes that the matter is complex, however, and such packaging innovations may have real utility in assuring the best results from effective technologies such as modified atmosphere packaging or vacuum packaging. In these technologies, high barrier materials are used to preserve the protective atmosphere or to avoid oxygen entry into the package from outside. In such well-confined environments (the headspaces of barrier packages), even a very small, 'physiological', level of off-flavours can reach high concentrations and lead to the rejection of safe foodstuffs. In such circumstances, use of active absorbing devices might be advantageous.

In the proposal, the expression of caution is limited to a generic point in Article 4: *...articles shall not bring about changes in the composition or the organoleptic characteristics of the food which could mislead the consumers.* A stronger principle might be introduced in the declaration in Article 3 (general requirements), that *materials and articles should not mask (by means of absorption, migration or other systems) an incipient spoilage of the food or beverage.* This also needs attention during the preparation of the specific measures for active and intelligent packaging.

(v) Testing procedures. Methods to test and guarantee the safety of active and intelligent packagings are still under development. The aspects relating to reference laboratories (as for some of the other aspects of the proposal relating to the procedures for regulation and authorisation) have already been addressed, discussed and approved in regulations concerning food safety (Regulation 178/2002) and are generally not considered controversial. However, developing and validating science-based testing in accordance with the rules for materials intended to come into contact with food is expensive and time-consuming. With regard to setting up reference laboratories, there has been uncoordinated progress across the EU among universities, research centres and private companies, and it would now be timely to implement a network of national and Community laboratories covering contact materials. The European Food Safety Authority will be important in giving market authorisation to active and intelligent packaging materials.

(vi) Labelling rules. The reviewers observed that there were some important issues for the consumers – to inform on what they are buying, why the product in new packaging has longer shelf-life than previous formulations, whether there are specific safety concerns (for example, inedible scavenger pouches) and how to read the information given in the intelligent packaging device

(for example, what can be concluded from the colour of the freshness or time-temperature tag). All the information should be provided on the consumer package in easily readable and clearly visible form.

One specific point raised by reviewers related to Article 12 on Labelling (1(b) safe use). Migration phenomena vary greatly according to the nature of the contact medium so that, for example, what is suitable for contact with foods having high water content may not be suitable for foods having high fat content. The principle of labelling the food contact material should take this into account, admitting the possibility of specific limitation in use. More general discussion and exemplification would be useful in other ways, for example, whether a product is suitable for microwave use.

ENVIRONMENTAL ASPECTS

Several reviewers advised that environmental aspects (recycling and production of waste) of active and intelligent packagings were not sufficiently discussed in the proposal and that the Commission Impact Assessment statement (page 28) was inadequate in its conclusion that *No social or environmental impacts are expected by this proposal*. Potentially, many active and intelligent packagings, by their nature and technical properties, contradict the waste management objectives of the EU Packaging and Waste Directive (94/62 EC, December 1994).

COMMUNITY AUTHORIZATION

Article 10 – who has the final word on authorisation, EFSA or the Commission?

OTHER POINTS RAISED BY REVIEWERS

Some consider the term 'organoleptic' is old fashioned and should be replaced with the term 'sensory' throughout the proposal (at least on pages 2, 7, 11).

Nanotechnology is currently one of the most important research areas in material science. Packaging scientists are keen to explore what properties can be designed and built into packaging material at the molecular level. The Commission should prepare to modify the Regulation when progress in nanotechnology leads to tangible, promising applications.

With reference to clause 6 of the proposal (page 8), what does 'antiques' refer to? Can these be exemplified and any specific safety issues discussed?

Article 1 section 3c (page 10) – the reference to 'fixed public or private waste supply equipment' is mentioned here for the first time. Further

explanation of this as a qualifying exclusion should be provided in the rationale.

Article 16 paragraph 2 (safeguard measures) – no timeframe is set for the Commission except the relatively vague phrase 'without delay'.

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