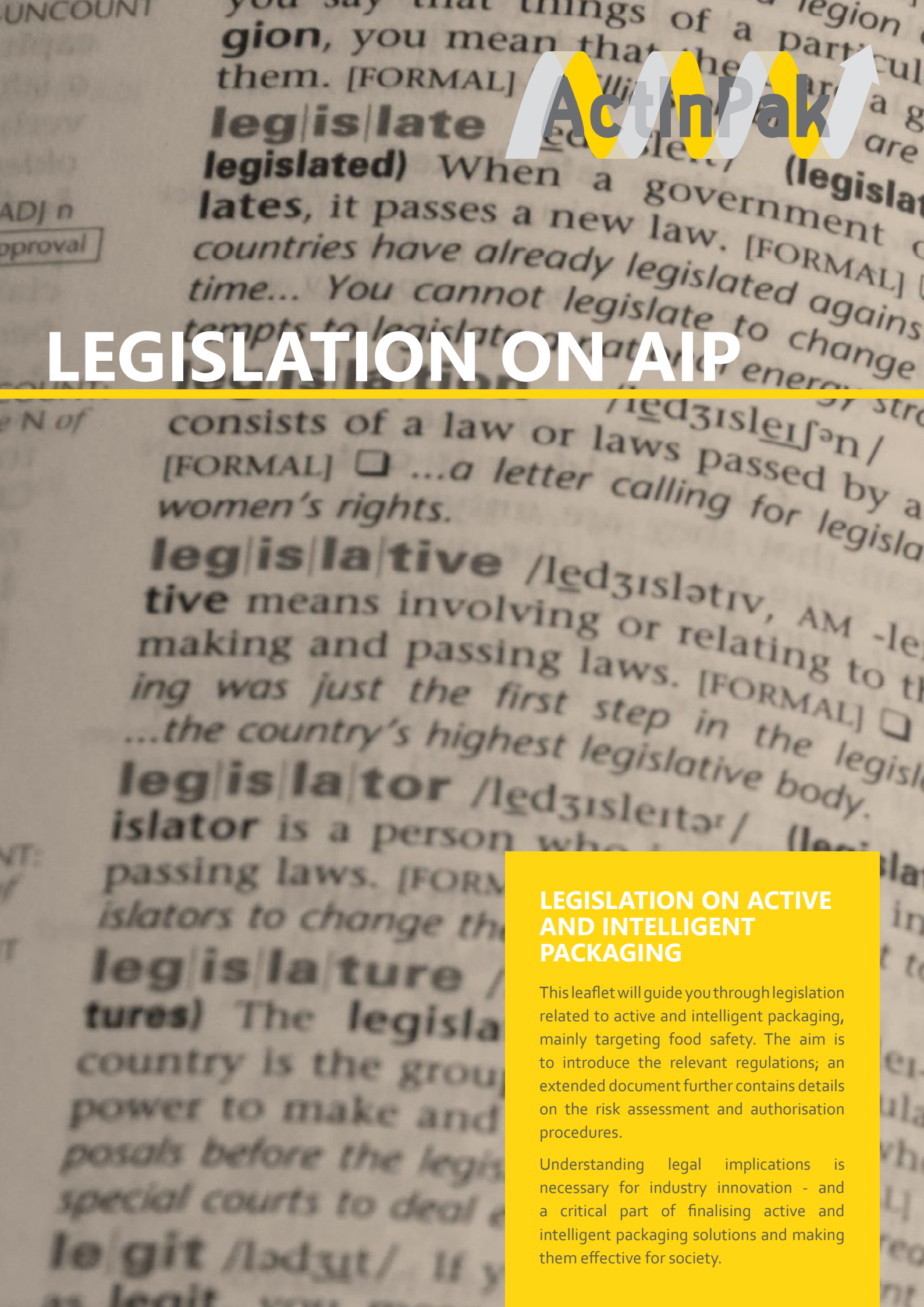


LEGISLATION ON AIP

LEGISLATION ON ACTIVE AND INTELLIGENT PACKAGING

This leaflet will guide you through legislation related to active and intelligent packaging, mainly targeting food safety. The aim is to introduce the relevant regulations; an extended document further contains details on the risk assessment and authorisation procedures.

Understanding legal implications is necessary for industry innovation - and a critical part of finalising active and intelligent packaging solutions and making them effective for society.

IN BRIEF

This leaflet describes legislation on active and intelligent packaging for food applications. For non-food applications other procedures might be in place; see the example on the right for more information.

In the European Union, active and intelligent packaging for food applications is considered a food contact material and must meet requirement of food contact material. Therefore it must comply with:

- **the general European Framework Regulation (EC) No 1935/2004 on Food Contact Materials,**
- **the specific European Regulation (EC) No 450/2009 on Active and Intelligent Materials,**
- **national rules, if they exist.**

The manufacturing process of active and intelligent materials should comply with Regulation (EC) No 2023/2006 on Good manufacturing Practices.

For the specific Regulation (EC) No 450/2009 on Active and Intelligent Materials it is important to define the "active part" of the packaging. Active materials and articles are intended to extend shelf-life or to maintain / improve the condition of packaged food. They deliberately incorporate components that release or absorb substances into or from the packaged food or the environment surrounding the food.

Both the components of the packaging which have an intentional "active" effect on food, and the substances they produce in the packaging by in situ reactions, must comply with the (EC) No 450/2009.

The rest of the packaging is "passive" and outside of the scope of Regulation (EC) No 450/2009; however, it is subject to Regulation (EC) No 1935/2004.

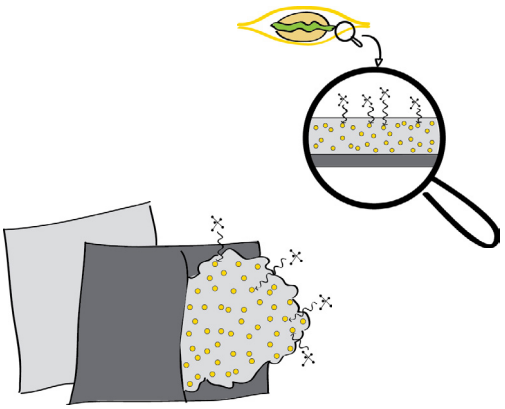
Safety of active substances present in packaging need to be evaluated by the European Food Safety Authority (EFSA) before their possible inclusion into a positive Community list. This list is foreseen but not yet available. Instead, a register of substances for which a valid authorisation application was submitted is accessible (see the last page of this leaflet).

Only individual substances and combinations of substances assessed by EFSA may be used in components of active and intelligent materials and articles.

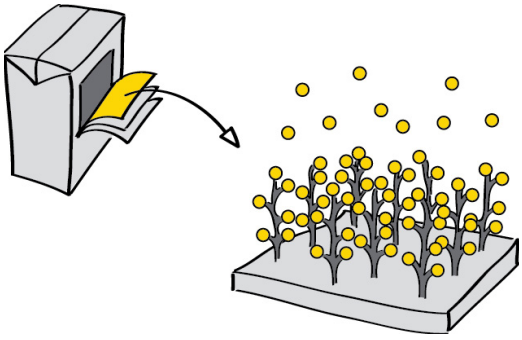
However, the EU Guidance document (link on last page) shows that suppliers, while in the process of having their active packaging approved, may place active and intelligent packaging solutions on the market provided all other applicable European and national regulations are complied with, demonstrating that they do not present risks to human health. From the date of application of the Community list, only packaging that comply with compositional requirements can be marketed.

EXAMPLES

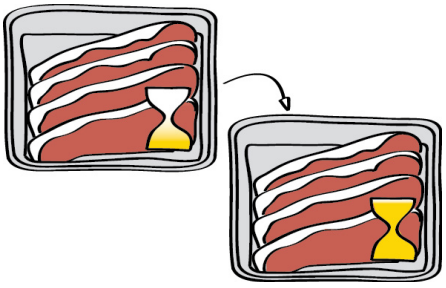
ABSORBING OR SCAVENGING SYSTEMS



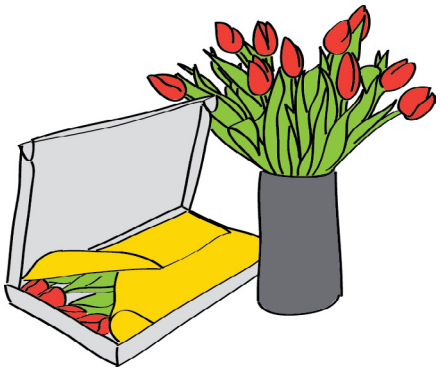
RELEASING SYSTEMS



INTELLIGENT PACKAGING



NON-FOOD



ABSORBING OR SCAVENGING SYSTEMS

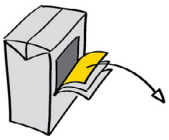
These come in different forms: 1) a sachet made of a laminated film containing an active powder to scavenge gas from the headspace of packaged foods, or 2) a film in which the active substance is blended with a polymer to form a modified gas absorber.

In both cases, the active substances in the sachet or film that are directly involved in the absorption process are the ***active*** substances, and should firstly be a safe Food Contact Material according to the European and/or national provisions on the basis of the nature of the material itself. Secondly, if the individual or combination of active substance(s) is not yet included in the Community list, it should undergo risk assessment under Regulation (EC) No 450/2009.

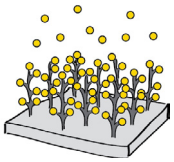
The sachet and film itself are ***passive*** and need to be safe Food Contact Materials according to the European Regulation (EC) No 1935/2004, EC specific measures if available, and/or national provisions on the basis of the nature of the material itself. If the role of the absorber is to prevent it from permeating from the outside environment through the package into the food, it is not considered and active packaging but a barrier enhancer and only Regulation (EC) No 1935/2004 applies.

RELEASING SYSTEMS

These refer to those materials which deliberately release substances, such as antimicrobials and antioxidants, in order to protect the food and reduce spoilage during shelf-life.



Since the antimicrobial is released from the material, it is considered ***active*** and should firstly be a safe Food Contact Material according to the European and/or national provisions on the basis of the nature of the material itself. Secondly, if the individual or combination of active substance(s) is not yet included in the Community list, it should undergo risk assessment under Regulation (EC) No 450/2009. Even if the antimicrobial is immobilised and incorporated by grafting, it is active if it deliberately influences the conditions of food without intentional migration.



Here the **passive** parts are the base substrate, biocatalysts, and any polymers which carry the active substances (as for films).These need to be safe Food Contact Materials according to the European and/or national provisions.

INTELLIGENT PACKAGING

If indicators are separated from the food by functional barrier and are not mutagenic, carcinogenic or toxic to reproduction, or in nanosize, no authorisation is needed. If an indicator is incorporated into the food contact layer, these are not intended to release their constituents into the food, it should undergo risk assessment under Regulation (EC) No 450/2009to request authorisation and inclusion in the Community list.

NON-FOOD

It is simpler to implement active and intelligent packaging technologies for non-food applications as Regulations (EC) No 450/2009 and Regulation (EC) No 1935/2004 apply only to Food Contact Materials. However, this does not mean there are no regulations.

Some non-food areas in which active and intelligent packaging can be of added value are pharmacy, cosmetics and flowers. For pharmacy, there are no specific rules about the admissibility of extra functionalities; as long as they do not interfere with the general packaging requirements they might be permissible to be produced by authorised producers after further assessment. For cosmetics, further assessment by legislative experts is necessary before the packaging can be placed on the market. For flowers, in addition to regulations on plant protection there is legislation on packaging that differs per country and flower type.

In all above cases it is relevant to consult an expert.

RELATED EUROPEAN REGULATIONS

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food
- Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food

MORE INFORMATION

- More information on legislation regarding Active & Intelligent Packaging can be found on the website of the European Commission via *tinyurl.com/EClegislationAIP*
- EU Guidance to the Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, via *tinyurl.com/EUguidanceAIP*
- Guidelines on submission of a dossier for safety evaluation by EFSA of active or intelligent substances present in active and intelligent materials and articles intended to come into contact with food, via *tinyurl.com/EFSAguidelines*
- Register of substances for which a valid application for authorisation was submitted under Regulation (EC) No 450/2009, via *tinyurl.com/AIPregister*
- List of substances assessed by EFSA, via *tinyurl.com/EFSAsubstances* (tab *completed work*)
- Food Contact Materials database, via *tinyurl.com/FCMdatabase*
- WG2 of COST Action FP1405 has prepared a full text with overview and some examples on active and intelligent packaging legislation. This full text can be found on our website *www.actinpak.eu* or by scanning the QR code on the left.

DISCLAIMER

This document does not replace the opinion of the authorities and does not intend to provide legal advice on issues of national law.

ABOUT ACTINPAK

COST FP1405 ActInPak aims to identify and overcome the key technical, social, economic and legislative barriers to a successful deployment of renewable fibre-based functional packaging solutions such as active and intelligent packaging. Currently, 43 countries are involved in the network, with participants representing 209 academic institutions, 35 technical centers, and 83 industrial partners. For more information, please visit the ActInPak website: *www.actinpak.eu*

COST (European Cooperation in Science and Technology) is a funding agency for research and innovation networks. Our Actions help connect research initiatives across Europe and enable scientists to grow their ideas by sharing them with their peers. This boosts their research, career and innovation. *www.cost.eu*

ActInPak

cost EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

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