International Standard

ISO 6608-1

First edition
2024-09

Active and intelligent packaging —

Part 1: General requirements and specifications of active packaging

Emballage actif et intelligent —

Partie 1: Exigences et spécifications générales relatives à l'emballage actif

Reference number
ISO 6608-1:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword

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This document was prepared by Technical Committee ISO/TC 122, *Packaging*.

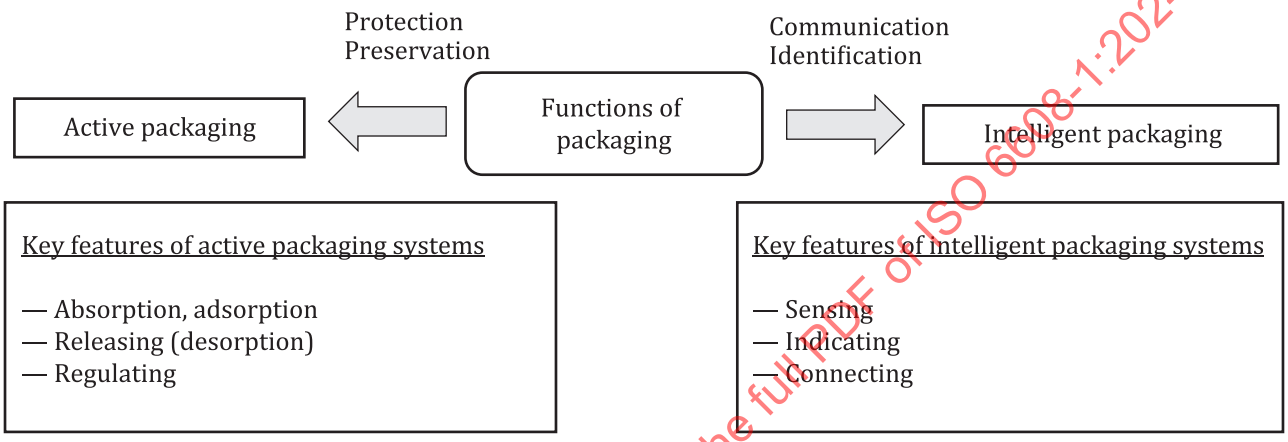
A list of all parts in the ISO 6608 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Active and intelligent packaging, frequently referred to as “smart” packaging, is evolving technology that can enhance preservation of contained products and communicate effectively to distributors and users. “Smart packaging” is a general term to describe a large category of packaging that leverages technology to provide enhanced functionality that goes beyond simply housing a product.

The role of active packaging and intelligent packaging is different. Active packaging is intended to sense internal or external environmental change and to respond by changing its own properties or attributes and hence the internal package environment. Intelligent packaging does not change or influence the contained products but is capable of providing information on the conditions of the packaged products. In general, the main function of active packaging is to extend the shelf life of a product while that of intelligent packaging is communication and identification.



As materials and communication technologies advance, more products and packaging involve active, intelligent packaging to enhance the product and user experience it contains. The main industrial sectors are food and beverages, but it is also applied to a variety of product packaging.

From a regulatory perspective, active and intelligent packaging is not subject to any special regulations in many countries, but there are general concerns regarding safety, especially on food contact materials. European regulation (EC) No 1935/2004, concerning a declaration of compliance and the availability of appropriate documentation, states that any active and intelligent material shall provide that the material is safe to be used in contact with food under specified conditions of contact.

Active and intelligent packaging (AIP) helps to optimize for transport and efficiency in logistics by providing interactive and accurate supply chain information. AIP is useful for improving safety and security of perishable and temper sensitive products such as vaccine and pharmaceutical industry. It helps companies in branding and marketing advantages. Ultimately, this technology helps to minimize the packaging and product waste by reducing unnecessary resources and product spoilage during distribution process. This document is intended to be used effectively in the development and use of related products in the future.

Active and intelligent packaging —

Part 1:
General requirements and specifications of active packaging

1 Scope

This document specifies the definitions, functional requirements and evaluation criteria of active packaging.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21067-1, *Packaging — Vocabulary — Part 1: General terms*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21067-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
product
first level or higher assembly that is sold in a complete end-usable configuration

[SOURCE: ISO 28219:2017, 3.8]

3.2
product package
packaging and its contents

[SOURCE: ISO 21067-1:2016, 2.1.3]

3.3
packaging component
part of packaging that can be separated by hand or by using simple physical means

[SOURCE: ISO 18601:2013, 3.11]

3.4
packaging constituent
part from which packaging or its components are made and which cannot be separated by hand or by using simple physical means

[SOURCE: ISO 18601:2013, 3.12]

3.5
active packaging
packaging system that actively interacts with the internal environment to extend product shelf life or improve safety or sensual properties while maintaining product quality

EXAMPLE A type of packaging that possesses barrier and protective qualities, such as oxygen scavenging, moisture scavenging, or microbial control, etc.

3.6
passive packaging
packaging with no active materials and components

3.7
active materials and components
materials and components that have the function of extending the shelf life or maintaining or improving the condition of a packaged product that is intentionally designed to contain components that release or absorb substances into the packaged product or the environment surrounding the product

3.8
sorption
physical and chemical phenomenon or process by which one substance becomes attached to another

3.9
absorption
physical or chemical phenomenon or process by which one state of matter is incorporated into another state (e.g. a liquid absorbed by a solid or a gas absorbed by a liquid)

Note 1 to entry: See Figure 1 a).

3.10
adsorption
physical or chemical phenomenon or process in which ions and molecules physically attach or bind to the surface of another phase (e.g. a reagent adsorbed on the surface of a solid catalyst)

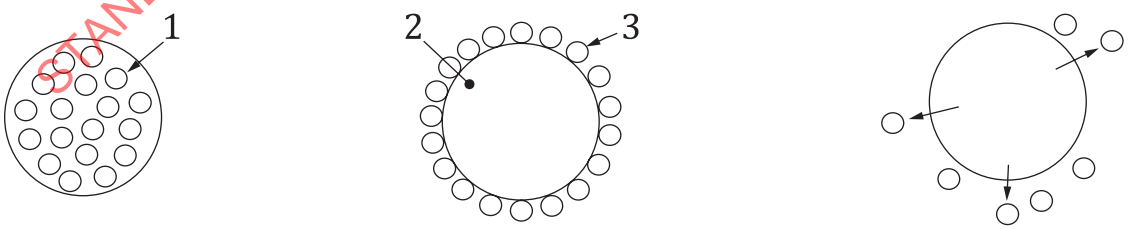
Note 1 to entry: See Figure 1 b).

3.11
desorption
physical or chemical phenomenon or process whereby a substance is released from a packaging material

Note 1 to entry: The process is the opposite of adsorption.

Note 2 to entry: See Figure 1 c).

[SOURCE: ISO 16559:2022, 3.66, modified — " or through a surface" has been replaced with "a packaging material", "and adsorption" has been removed from the Note 1 to entry.]



a) Absorption **b) Adsorption** **c) Desorption**

Key

1 absorbed molecules
2 adsorbent
3 adsorbate

Figure 1 — Concept of absorption, adsorption and desorption

3.12
releasing
action to let going into environment or free movement of active materials and components

3.13
regulating
action to controlling or maintaining the rate or speed of active materials and components so that it works properly

3.14
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word "verified" is used to designate the corresponding status.

3.15
certified reference material
CRM
reference material accompanied by a certificate, one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body

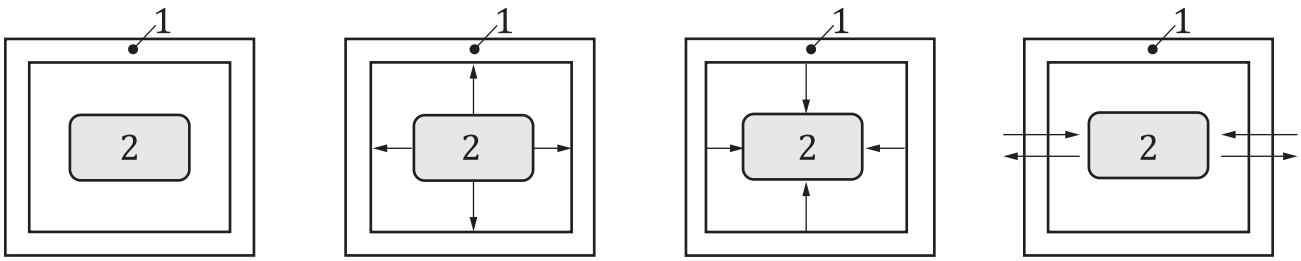
[SOURCE: ISO/Guide 33:2015, 3.2]

3.16
modified atmosphere packaging
MAP
enclosure of food in a package in which the atmosphere inside the package is modified or altered to provide an optimum atmosphere for increasing shelf life and maintaining food quality

4 General

4.1 Concept of active packaging

The mechanism of the packaging system can be characterized as a) passive, b) adsorption/absorption, c) release, and d) regulation as shown in Figure 2.



a) Passive **b) Adsorption / Absorption** **c) Release (desorption)** **d) Regulation**

Key

1 packaging

2 content

NOTE Passive packaging is not a part of this document.

Figure 2 — Characteristics of packaging system

The application of active materials and components to packaging is intended to have a positive effect on the packaged product. The packaging adsorbs chemicals from the product or the environment within the packaging surrounding the product, or it releases substances into the product or the environment surrounding the product such as preservatives, antioxidants, flavourings, etc.

Active packaging typically involve packaging materials, packaging components, and/or packaging constituents that contain a variety of active substances that are incorporated into the packaging material's formulation. These substances improve the packaging material's ability to extend the shelf life of the product contained inside.

Hence, structurally, active packaging consists of two parts. One part includes the active components, while the other part concerns the carriers or passive parts that contain the active component.

NOTE In case of an ethanol releaser, the ethanol is absorbed onto a silica gel, which in turn is packaged in a paper or plastic sachet. The ethanol is defined as the active component evaluated in this process. Passive packaging materials with a simple barrier function are not covered by this document.

4.2 Classifications

There are many different types of active packaging systems such as oxygen scavengers, moisture absorbers, etc. The classification of active packaging is divided into three functions: sorption, release, and regulation. Types of active packaging systems according to the active functions are shown in Annex A.

5 Evaluation

5.1 General criteria

To declare that a packaging is an active packaging, the manufacturer and/or seller shall

a) evaluate chemical and microbiological safety;

b) provide reliable test results to prove shelf-life extending capacity, efficacy of active systems;

c) complete toxicological, economic and environmental evaluation;

d) confirm compatibility with existing manufacturing processes;

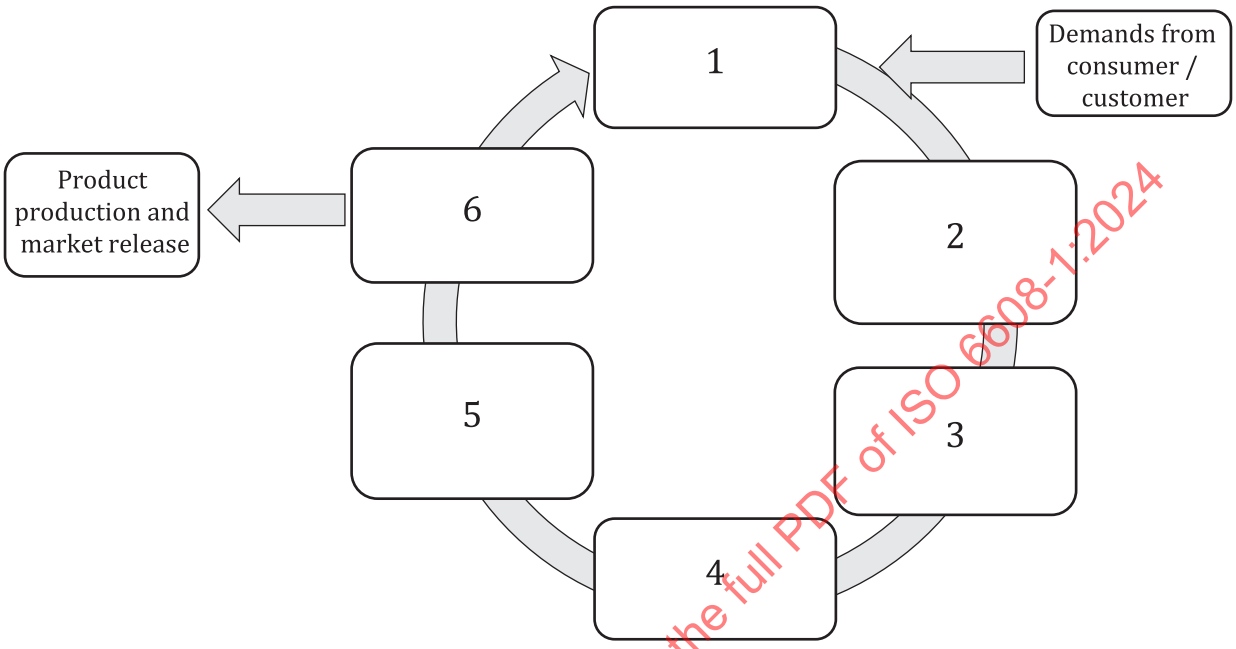
e) confirm that it does not modify organoleptic properties of foods;

f) confirm that it shall activate as needed.

5.2 Process model for active packaging evaluation

5.2.1 General concept of evaluation process model

Process model for active packaging evaluation is as shown in Figure 3.



Key

1	define intended usage and active functions	4	perform safety and toxicological tests
2	determine test methods and acceptable criteria	5	confirm the labelling and environmental requirements
3	validate and verify active functions of packaging components	6	complete the check list and submit the report

Figure 3 — Evaluation process of active packaging

a) Define intended usage and active functions: Prior to developing and placing an active packaging on the market, the packaging supplier shall identify the function, usage and method of use according to the target market.

b) Determine test methods and acceptable criteria: Determine the necessary requirements and test and evaluation methods according to the function, method, and market to be used.

c) Validate and verify active functions of packaging components and/or packaging and improvement of packaging performance: Collect or generate the data necessary to review the active function and adaptability of a substance as a packaging material.

d) Perform safety and toxicological tests: Check safety and confirm existing regional and international regulations (toxicological, chemical, biological, etc.).

e) Confirm the labelling and environmental requirements: In addition to checking the environmental requirements required by the regional and international authorities, it is recommended to label the packaging to identify what kind of substance has been added.

f) Complete the check list and submit the report including test results.

5.2.2 Defining functions and intended use

In order to be evaluated as an active packaging, the function, intended use and field of application shall be clearly stated. For example, it is necessary to clearly indicate whether the applied product is food, whether the purpose is to extend the shelf life, or to provide a function, so that it can be evaluated according to the purpose of use.

5.2.3 Evaluation of active functions

5.2.3.1 Evaluation of packaging material properties

Material property evaluation can verify mechanical, physical, thermal and chemical properties. Examples of test methods for packaging material properties are shown in Annex B, Table B.1.

5.2.3.2 Collection/generation of the data required

Reliable data should be collected in a scientifically sound manner depending on the functional use, such as oxygen scavenging, antibacterial and antioxidant properties, and selective gas permeation properties, etc. The data that should be collected according to the function of the active packaging are shown in Annex B, Table B.2.

5.2.4 Safety

Active packaging shall be suitable and effective for the intended purpose.

Packaging suppliers and manufacturers must provide evidence that the active ingredient complies with specification restrictions, particularly for food contact substances, including overall migration limit (OML), specific migration limit (SML) and toxicity profile assessment.

Any substance or article that comes into direct or indirect contact with food is subject to a level of risk to human health whose constituents can change the composition of food or deteriorate the organoleptic properties of food under normal and foreseeable conditions. The risks posed by the adoption and use of technologies such as nanoparticles require specific analysis of the interactions between food and human health.

The active substances may be transferred to product within the legally permissible range of the substance. However, it should not affect the characteristics of the product.

Even in the case of an approved substance integrated with the immobilization technology of the active substance, if a chemical reaction, decomposition or decay is expected, the manufacturer's safety evaluation and verification of the substance's stability are required.

6 Labelling

To declare active packaging, the label shall indicate the active substance it actually contains, its active state and its visible effect. Labels shall indicate sanitary, toxic and recycling or segregation methods.

Labelling of products packaged with active substances and articles containing substances released into the product shall be carried out in accordance with the relevant labelling regulations. For example, to avoid the contents of a sachet being perceived as edible, the active ingredient shall not be misleading to the consumer, and the label contains the sentence or symbol "Do not eat" to prevent accidental ingestion.

Released active substances are considered ingredients. Food additives are subject to general labelling obligations under regional and national regulations relating to the labelling and advertising of products.

In order to ensure the correct use of these packaging materials and containers, not only consumers but also all stakeholders should be informed properly about the product package containing active substances and products that have not come into contact with food when placed on the market, for example, antioxidants released from food, their permitted uses and information on the name and maximum amounts of antioxidants

released from the active ingredients. This should be accompanied by other relevant information, such as the use of these ingredients and their acceptable levels in the product.

7 Environmental consideration

Especially in the food industry, active packaging can have a positive impact on the environment by contributing to minimizing product waste. However, packaging materials and technologies applied to active packaging can adversely affect the recycling process, so they shall be separated and discharged, and consumers should be able to easily remove them.

Active packaging should be designed to comply with ISO 18602, ISO 18604 and ISO 18605 to ensure that it is easily separated from other materials and/or does not degrade recycled materials.

8 Test report

After the active packaging evaluation is completed, the following information shall be included in a test report:

a) the sample information;

b) the date of the test;

c) the name, position and signature of the person that approved the test report;

d) a reference to this document, i.e. ISO 6608-1:2024;

e) the result(s), the procedures and test methods with documentation to include, but is not limited to:

- a description of the analytical methods used, including sample preparation, extraction and analysis;
- a description of the preparation of calibration standards, QCs, blanks, etc.;
- a description of the potential interference;
- a summary of tests performed to determine accuracy, precision, recovery, selectivity, quantification and calibration limits;
- a signed statement indicating the suitability of the method for its intended purpose;

f) any deviations from the procedure and any unusual features observed.

Annex A
(informative)

Types of active packaging systems by different functions

Based on the functions, different types of current active packaging systems are categorized and described in Table A.1.

Table A.1 — Functions of different types of current active packaging systems

Function	Type	Description
Sorption	Oxygen scavengers	— Removing the oxygen in a package. It is mainly applied to products that react sensitively to oxygen, and provides product safety by preventing oxidation and inhibiting enzymatic browning, improving quality and inhibiting the generation of aerobic putrefactive mold and harmful bacteria. The activity of the oxygen scavenger should be in the form of self-activated, moisture activated, or activated oxygen neutralized when exposed to UV irradiation.
	Moisture absorbers	— Absorbing the moisture for the proper quality conditions of the products. Moisture adsorbents reduce the water activity of packaged products and improve the quality that affects the physical and chemical reactions caused by water. In general, moisture softens the tissue structure of the product, causes deterioration of quality such as the growth of decaying microorganisms, and affects non-enzymatic browning or colour change of product. For most moisture-sensitive products, in order to minimize product quality degradation during distribution, a dehumidifying product including a separate dehumidifying material is packaged and applied with the target product. In addition, the form of applying the dehumidifying material to the product is applied in the form of a sachet, a tray pad or sheet, a packaging container closure, etc. inside the packaging.
	Ethylene scavengers	— Preventing the cause of deterioration metabolism of fresh produces. Ethylene is generated along with the respiration of fresh fruits and vegetables, and increases metabolism after harvest, resulting in quality changes such as aging. Removal of the ethylene generated around fruits and vegetables slows down the aging metabolic rate to secure a long shelf life along with refrigerated distribution. Packaging is applied in the form of impregnating the ethylene removal material into the film or in the form of a sachet. A method exists consisting of oxidizing potassium permanganate or adsorbing and removing it with zeolite, alumina, activated carbon, or the like.

Table A.1 *(continued)*

Function	Type	Description
	Odour and flavour scavengers	— Removing unwanted odours and flavours. It can be considered for the purpose of removing undesirable taste or flavour components and packaging materials from the packaged product and removing unwanted additives or odour compounds from the packaging material or preventing material transfer. Amine-based alkali compounds generated from proteins such as packaged seafood have strong unpleasant odours, odours of aldehydes and ketones decomposed as a result of automatic oxidation of fat, and hydrogen sulphide (H2S), which is generated as a result of decomposition, lowers the quality of products and affects the commercial value and have a big impact. Silica gel, activated carbon, bivalent ferrous compound, and organic acids such as citric acid or ascorbic acid, which have the function of adsorption and removal, are used alone or impregnated with packaging materials. It is also a necessary function to solve the odour of volatile organic compounds (VOCs) generated from recycled plastics.
	Carbon dioxide scavengers	A large amount of carbon dioxide is emitted due to the ripening of roasted coffee or kimchi and the respiratory metabolism of fruits and vegetables, so it shall be removed to prevent spoilage of food and damage to food packaging materials through packaging. In addition, carbon dioxide is applied for the purpose of inhibiting the growth of microorganisms on the microbial surface of processed foods such as nuts, snacks, cakes, and cheese.
Release (desorption)	Antimicrobial compound	— Inhibiting the harmful microbial growth to affect the quality and safety. The main cause of spoilage of most products is the growth of harmful microorganisms on the product surface. Antibacterial packaging inhibits the growth of microorganisms by transferring antibacterial substances applied to the inner surface of the packaging by impregnation or coating to the contents. If the antibacterial material is transferred to the surface of the contents from the packaging material and suppresses the growth of harmful microorganisms, there is an advantage in that the amount of the preservative directly applied to the contents can be reduced and the effect of quality preservation can be obtained. Antibacterial materials applicable as packaging materials are largely inorganic materials, such as silver zeolite, and organic materials such as organic acids such as sorbic acid, propionic acid, and benzoic acid, chitosan materials, and natural compounds such as wasabi extract or grapefruit seed extract.
	Antioxidant	— Preventing the lipid oxidation that is the cause of product degradation. Oxidation of the product exposed to the environment affects the quality of the product. It is a transition process with the principle of diffusion and vapor phase evaporation to the surface of the film polymer by impregnating the packaging material with an antioxidant material or coating it. As antioxidant materials applicable to packaging, natural antioxidants such as ascorbic acid, tocopherol, and non-enzymatic browning products, or phenolic synthetic antioxidants such as BHT(Butylated hydroxytoluene), BHA(butylated hydroxyanisole), and TBHQ(tert-butyl-hydroquinone) in a certain amount are used in the production of antioxidant packaging films.

Table A.1 *(continued)*

Function	Type	Description
Regulation	Gas regulators	Modified atmosphere packaging (MAP) is a packaging system that constitutes an optimal gas environment condition for maintaining the freshness of fresh products, and the optimum condition has a different gas composition and is configured differently depending on the quality characteristics of the products. MAP, which is applied to fresh fruits and vegetables and processed food, has already been commercialized, and widely used MAP processing technologies include vacuum packaging, gas replacement packaging, selective permeation packaging and micro-perforation technology.
	Heat regulators	Self-heating packaging is mainly applied for the convenience of heated foods, and uses calcium or magnesium oxide that causes an exothermic reaction with water, and is used for convenience foods, coffee cans, and instant rice. Various refrigerants containing a phase change material (heating/cooling) that gives a function of maintaining a constant temperature in a low-temperature state inside the packaging together with insulating packaging materials have been commercialized and are widely used in distribution processes.