



**Saudi Standards, Metrology and Quality Organization
SASO**

Technical Regulation for Degradable Plastic Products

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Note:

**Only the Arabic version of this Regulation is authentic in law and is
applicable where there are differences with this translation**

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Foreword:

In line with Saudi Arabia's accession to the WTO, as per The Saudi Cabinet Decree 244, dated 09/21/1426 AH concerning the approval of documents of The Kingdom's accession to the World Trade Organization, and the related consequent commitments concerning the Kingdom's harmonizing of its regulations to cope with the principles of the WTO Conventions , especially technical barriers to trade agreement (TBT) that dictates setting no unnecessary technical requirements that may block the flow of goods between Member States, and non-discrimination between products originating in different countries in terms of technical requirements and methods of conformity assessment, and by issuing technical regulations that include basic requirements and unified business processes.

Based on Article III (paragraph - 1) of the Saudi organization for Standards, Metrology and Quality SASO issued by the Saudi Cabinet Decree 216 dated 17/06/1431 H corresponding to 31/5/2010 m , SASO is concerned with "issuance of Saudi standard specifications , systems , quality manuals and conformity assessment, compatible with international standards and guidelines , that fulfills WTO requirements while complying with Islamic Sharia and considering achievement of the Kingdom welfare. "

Based on Article IV (paragraph - 2) of the Saudi organization for Standards, Metrology and Quality SASO issued by the Saudi Cabinet Decree 216 dated 17/06/1431 H corresponding to 31/5/2010 m, SASO is to "issue regulation for conformity assessment procedures for goods, products and services according to the standard specifications that it approves. "

Based on Article VI (paragraph - 14) of the Saudi organization for Standards, Metrology and Quality SASO issued by the Saudi Cabinet Decree 216 dated 17/06/1431 H corresponding to 31/5/2010 m, SASO is to "revise all controlling systems and regulations related to SASO's areas of interest, develop it, suggest the suitable modifications to cope with the quality and safety requirements , introduce it to the concerned bodies , for further study , approval and issuance via official channels."

Based on Article VI (paragraph - 14) of the Saudi organization for Standards, Metrology and Quality SASO issued by the Saudi Cabinet Decree 216 dated 17/06/1431 H corresponding to 31/5/2010 m, SASO "While considering the provisions of article 4 of this regulation, SASO is considered the only authority in all the issues related with standards in the kingdom, also conformity assessment procedures, granting quality marks , measurement and calibration. Consequently, all governmental and private sectors must adhere to the Saudi standard specifications in all their procurement procedures. "

Whereas the standard specifications of the products subject to a regulation are considered - among others- the basis for the products conformity with the essential requirements for safety, in the specified regulation.

This Technical Regulations are prepared by SASO.

Note: This foreword and all annexes are an integral part of this regulation.

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Article 1: Terms and Definitions

1/1 When applying the articles of this regulation, the terms and expressions, given below, shall have the meanings specified in front thereof, unless the context otherwise requires:

KSA: The Kingdom of Saudi Arabia

SASO: Saudi Standards, Metrology and Quality Organization (SASO)

The Board: SASO's Board of Directors.

Market surveillance Authorities: are the authorities / government bodies responsible for carrying out market surveillance measures.

Regulatory authorities: are the authorities / government bodies with regulatory tasks dictated by their specializations, and that are consequently responsible for the implementation and follow up of technical regulations either in the customs ports, markets or in factories.

Technical Regulation: A document approved by the Board of Directors that specifies the characteristics of products and their related processes and methods of production, including the applicable valid administrative provisions; that must be adhered to. It may include – or may search to introduce, justify or suggest- terms and definitions, packaging, and marking or logo requirements for on products, services or processes or production methods.

Standard: a document established by consensus (general agreement) and approved by a recognized body (responsible for standards and regulations- legal or administrative entity that has specific tasks and composition) that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

In the context of this regulation it is a document specifying the characteristics of the good, material, service or whatever subject to measurement. The standard also offers descriptions, characteristics, level of quality or dimensions and measurements and safety and security requirements. It also includes terminology, symbols, test methods and sampling techniques, packaging, logo and marking.

Essential requirements: the special requirements of the products; that may affect the safety, health and the environment; and that must be adhered to.

Market surveillance: activities and measures taken by the market surveillance authorities to verify that products meet the requirements set in the relevant technical regulations, and that they do not pose a hazard to health, safety and environment, or any other aspect related to the protection of the public concern.

Hazard(s): A potential source of harm.

Risk (s): A potential hazards causing damage; related to the severity of damage.

Supplier:

- product manufacturer, in case he is resident in the Kingdom, or the person identified as the manufacturer of the product through relating the product to his name or to a relevant commercial description, as well as a person that provides the product renewal.
- Agent of the Manufacturer in the Kingdom in the case the manufacturer is resident outside the Kingdom, or importer in the absence of an agent to the manufacturer.
- Any of the supply chain partners, whom activities may impact the product characteristics.

Conformity Assessment Procedures: A document approved by the Board of Directors describing the procedure used directly or indirectly for conformity assessment.

Notified Body: conformity assessment authority notified by the organization in accordance with conformity assessment bodies acceptance regulations.

Certificate of Conformity: certificate issued by the Commission or by one of the notified bodies; that confirms the product or a specific patch of the product is matching the requirements of the relevant standard.

supplier declaration of conformity: declaration from the supplier himself - without any mandatory intervention of a third party in the design phase or in the manufacturing processes- that his product is identical to the requirements of the applicable regulations. The declaration may be based on results of tests performed on the product in accordance with the relevant legislations.

Conformity Certificate: A certificate issued by SASO or a notified body, which ensures the conformity of a product, or any batch thereof, with the requirements of the relevant standards.

Saudi Quality Mark: A mark approved by SASO, confirming that an establishment has an effective management system ensuring the production of a commodity in conformance with the relevant regulation, certification procedure and Saudi standard.

Products: Degradable Plastic Products via OXO degradation then biotic degradation.

Consumer: Any normal person who got the product directly or through a service and uses it for personal purposes, for his family members, or his property.

Placing on the market: Means the first time a product becomes available on KSA market, under responsibility of the manufacturer or importer.

Making available on the market: Means any supply of product for distribution, consumption or use in the KSA in the course of a commercial activity, whether in return for payment or free of charge.

Withdrawal: Any procedure aiming to prevent products from being available in market and supply chain.

Recall: Any procedure aiming to recall products made available for the final user.

Bio-Degradable Plastics: A degradable plastic that when degraded results in water, carbon dioxide and biomass as a result of the micro-organisms that occur naturally.

OXO (oxo-degradable plastics): A plastics type that degrades when exposed to certain environmental conditions, to produce smaller parts of molecular weight (fragment parts). This degradable plastics type can be classified based on its exposure time. This has to be according to the appropriate standard test method.

Logo: SASO owns the degradable plastic Logo which is installed on products according to the requirements of this regulation. This Logo indicates the product's conformity with this regulation. Annex (6) includes its specified shape.

Licensing the Usage of the Logo: This is a license issued by SASO, a notified body or a body authorized by SASO. The license is to use a Logo and fix it on the products that meet the requirements of this regulation, including the requirements of related Saudi standards.

Registered Laboratory: A laboratory accredited based on ISO 17025 by an approved body in the field of degradable plastics testing. This lab is registered by SASO in order to approve the reports issued by it in the procedures of licensing a Logo usage.

Test Report: A test report issued by a registered laboratory, provided that the date of issuance does not exceed one year at the time of applying for the license.

2/1 The terms and expressions specified herein shall have the meanings specified in the applicable laws, regulation and decrees of SASO.

Article (2): Scope

This regulation applies to all the disposable products manufactured from polypropylene and polyethylene plastics which are often used for a short time listed in Annex (1). This disposal by degradation is according to thickness limits stipulated in the approved standards in Annex (2). This regulation makes obligatory that the products are OXO degradable then bio-degradable; in accordance with relevant definitions and terms provided in Article (1) and in accordance with relevant standards provided in Annex (2).

Plastic products used in the medical and food industries are an exception.

Article (3): Objectives

This regulation aims at determination of the specific environmental requirements of the degradable plastic products included in the scope of this regulation, for the sake of preservation of the environment, preservation of the health of human consumers and of animals, and to facilitate market surveillance procedures.

Fulfillment of the requirements of this regulation does not revoke adherence to requirements of the related technical regulations concerning safety of product.

Article (4): Requirements of Licensing the usage of the OXO Logo

SASO shall grant the license to use the OXO Logo if the following terms are fulfilled:

- A)** The supplier is officially registered at the official competent authority and having a commercial registration number.
- B)** The product fulfills all conformity assessment procedures that prove meeting all the requirements of technical regulations regarding the product safety.
- C)** The product is included in the scope of this regulation and meeting all of its requirements and of the requirements of standards specified in Annex (2).
- D)** The manufacturer shall have an effective Environment Management System EOS. ISO 14001 certification fulfills this requirement.
- E)** The supplier shall provide the Conformity Declaration provided in Annex (4).
- F)** The supplier shall provide a test report from a registered laboratory based on the form provided in Annex (5). The report shall meet the requirements of this regulation and relevant standards.
- G)** The supplier shall cooperate with the Regulatory Bodies and with market surveillance authorities. For example, provision of the technical file documents, the test reports and any

other documented information proving fulfillment of the requirements of licensing the Logo usage, where needed.

- H)** The manufacturer shall only use the additives licensed by SASO, in products manufacturing. The additives used for products in contact with food shall be safe for food, according to relevant standards. Documents proving this shall be provided.
- I)** All information used in the Logo shall be correct and proven.
- J)** Logos placed on a product shall meet the requirements of this regulation and The Saudi standards in this concern, particularly, the requirements of the manufacturing date and shelf life of the products covered by this regulation.
- K)** Usage of the Logo shall be as provided in Annex (6).

Article (5): Steps of Obtaining the License of Logo Usage

5/1 Application

A supplier shall follow the following steps to get a license to use the Logo:

- A)** Apply to SASO an individual separate application for every product intended to be licensed.
- B)** Submit a hard copy of the valid commercial or industrial license issued by a competent authority.
- C)** Fill the approved forms of the authority concerned with the product and supply this authority with any other additional documents when requested.
- D)** Attach the technical file including test reports proving the product's conformity with the requirements of this regulation, issued by a registered laboratory. A copy of the laboratory valid accreditation certificate shall be attached. Test reports shall include the following:
 - 1)** Abiotic Degradation Test Report.
 - 2)** A test report with the results of chemical analysis of residual material and the non-degradable fraction.
 - 3)** A test report of final aero-biodegradation.
- E)** Attach conformity assessment documents which prove that the product meets safety requirements of the relevant Saudi technical regulation.
- F)** Provide last year statistical data, for the amounts of local plastic products from the two types: Degradable and non-degradable (in kilograms). SASO shall keep this information confidential.
- G)** The supplier shall provide SASO with any information related to the product applied to get the license for. The supplier shall also facilitate getting a representative sample of the product, when needed, to verify its compliance with the requirements of this regulation, and at his expense.
- H)** The supplier shall declare that all information provided by him to SASO are valid and that he is responsible for.
- I)** The supplier shall pay SASO the costs of licensing the Logo usage.

5/2 Licensing the Product

SASO shall perform the below procedures to license the Logo usage:

- A) SASO shall examine the documents according to the licensing procedure approved for each product in order to verify all licensing requirements are met.
- B) SASO shall verify to what extent the product meets the requirements of this regulation, according to conformity assessment form (1a) “model accreditation” set out in Annex (3).
- C) SASO shall license the Logo usage after the product’s full compliance with all the requirements set forth in this regulation.
- D) In case of refusing the supplier’s application, He shall be informed in writing, with an explanation, - for the reasons of application refusal.
- E) SASO shall issue the license when the supplier meets all requirements and fulfills all required corrections within the period specified in the procedures of licensing the Logo.
- F) A competent regulatory agency shall have the right, when necessary, to take samples from random consignments of imported or locally manufactured products and test them in a registered laboratory, provided that the supplier bears the costs of sampling, testing and related matters.
- G) Validity period of Logo usage License for the product shall be one renewable year, provided that the supplier submits a renewal application at least one month before the expiration date.

5/3 Terms of Fixing a Logo

- A) The Logo shall only be fixed on licensed products in a clear position at the lower part. In case of bags, Logo shall be fixed on both sides of the bag to be indelible and to occupy 10 - 15 % of total space of both sides. In case of little-sized products that are hard to print on, Logo shall be fixed on the package, after SASO’s approval.
- B) A supplier shall be allowed to announce the license of Logo usage in his commercial transactions to prove that the products are licensed and subject to SASO’s follow-up.
- C) License or Logo shall be used only for the licensed products. A supplier shall be prohibited from using the license or Logo misleadingly or incorrectly in any other way deemed misleading by SASO or the Regulatory Bodies.
- D) Verify that the packaging materials of products are carrying the Logo.

Article (6): Metrological Requirements:

SI units, parts or multiples thereof shall be used.

Article (7): Logos

- a) Logos of degradable plastics, prepared to be fixed and displayed in the market, shall be written in Arabic or in both English and Arabic in a clear and difficult to remove manner.
- b) Logos shall conform with the technical requirements identified in this regulation and in the relevant standards.
- c) Each piece shall contain – in an eligible and non-erasable manner- the following information in Arabic or English or both:
 - 1) Manufacturer’s name and the trademark or any of them.

- 2) Country of origin and whether the product was manufactured under a license from a registered trademark / the manufacturing company.
 - 3) Production date; day, month, year, and barcode.
 - 4) Purpose of use and type of application.
 - 5) Shelf life and storage conditions.
 - 6) The Logo that indicates that the product is degradable, on each piece of the product.
- d) The Logo shall only be fixed on the licensed products in accordance with clause (3/5) of Article (5).
 - e) All information used in the markings shall be valid and proven.
 - f) Images or expressions used on product packages shall not violate the public law, morals and the Islamic values prevailing in the KSA.

Article (8): Responsibilities of Regulatory Bodies (outlets - factories)

As a part of its competence and powers, Regulatory Bodies shall:

- a) verify the procedures of fixing the Logo to products subject to this regulation and verify the Logo data.
- b) Randomly, sample the products subject to this regulation and refer such samples to specialized laboratories to check the extent of conformity with the requirements defined herein.
- c) Charge the suppliers with the costs of testing and the associated fees.
- d) Withdraw the non-conforming products from warehouses and take legal actions, in case of finding that the procedures of fixing the Logo were incorrect.
- e) The Regulatory Bodies shall verify that the products - subject to this regulation - are licensed and Logoed by SASO.

Article (9): Responsibilities of Market Surveillance Authorities

As a part of its competence and powers, market surveillance authorities shall:

- A. Apply the market surveillance procedures to the products available in the markets and on the products stored in warehouses in order to check correctness of Logo fixing procedures on products subject to this regulation and check the correctness of data.
- B. Sample the product, either from the market or warehouses of suppliers (manufacturers, importers, and distributors) to perform the required tests and check conformity with the requirements stated hereof. The supplier shall bear the costs of sampling, shipping and testing the samples, taken to guarantee the continual conformity with the related standard and this regulation.
- C. in case of non- conformity of displayed or stored – product, with the provisions of this regulation, market surveillance authorities shall take all administrative actions including the withdrawal and recall of the–product. Procedures and penalties referred to in Article (9) shall be applied, after taking the necessary actions.

Article (10): Violations and Penalties

- A) It is prohibited to manufacture, import, place in the market, demonstrate in a showroom or even advertise the products non-conforming with the requirements of the articles of this regulation.
- B) Non-fulfillment of the product for the requirements of this regulation is considered a sufficient reason to judge the product as incompatible by the market surveillance and regulatory authorities. This judgment means that the product may cause danger to consumer health and safety and the environment, in the following cases (not exclusive):
- 1) Incorrect fixation or non-fixation of the Logo.
 - 2) Lack, unavailability or incompleteness of technical documentation.
 - 3) Lack, unavailability or incompleteness of product data or usage guidelines.
- C) In case of non-conformity to the provisions of this Regulation, the market surveillance authorities - depending on the situation – shall take all the necessary measures to remove the violations and their effects on the market. In this concern the market surveillance authorities may:
- 1) Forcing the violating, non-conforming party; responsible for producing, placing in the market, or demonstration in a showroom, to withdraw the product from stores or from the market with the aim of correction or –if possible- re-exporting or destruction (according to the nature of the product), during the period determined by the market surveillance authorities.
 - 2) Withdrawal, seizure or destruction of products, or any other action to recall from the markets. Market surveillance authorities -depending on the situation – may announce of the product recall from the market, and the non-confirming party shall pay for all the costs .
- D) In case of non-conformity of the product, the Commission shall take the necessary measures concerning products non-conforming with the requirements of this regulation, including the cancellation of the license to use the Logo
- E) Without prejudice to any more severe penalty provided by the regulations in force, the supplier violating the provisions of the regulations shall be punished by penalties stipulated in the valid Commercial Fraud system, or any other system that replaces it.

Article (11): Financial Costs

(All costs shall be in Saudi Riyal (SR))

| S. | Clause | Costs |
|----|--|----------------------|
| 1 | Application Costs | 500 |
| 2 | Elementary Technical Documentation Study Costs | 2500/ business day |
| 3 | Costs of Licensing Logo Usage | 600 for each product |

Article (12) General Provisions

- 1) The supplier bears full legal responsibility for the implementation of the requirements of this regulation, penalties provided by the commercial fraud system or any related systems, shall be applied to him, if proven to violate any of the articles of this regulation.
- 2) This regulation does not prevent the supplier's commitment to all other systems or regulations in force in the Kingdom; concerned with the handling, transportation and storage of the product, as well as systems and/ or regulations related to the environment, security and safety.
- 3) All suppliers of the product subject to the provisions of this Regulation, shall provide inspectors of regulatory and market surveillance authorities with all the facilities and information they require to carry out their assigned tasks.
- 4) Were new originated situations that cannot be treated under the provisions of these Regulations, or were a dispute arises as a result of the application of articles of the regulations, the matter is unfurled to a committee set up in the Commission to issue the appropriate decision in this case or dispute, considering the community interest.
- 5) The supplier can submit a new application after the demise of the reasons for rejection of the application, and after making the necessary corrections for the reasons that led to the refusal, and the payment of any additional costs determined by the Commission.
- 6) The Board shall examine the complaints, it receives concerning products having conformity certificate or quality mark, through specialized committees, where validity of these complaints is checked and consequently legal systematic actions taken, in case a violation proved.
- 7) the commission is authorized to cancel the conformity certificate or the license to use the quality mark if the supplier violates the terms of this regulation, and to take legal action to ensure the preservation of the community rights.
- 8) Were modifications performed on the product during the period of validity of conformity certificate, or license to use the quality mark (except modification in shape) the certificate or license be canceled for this product, and supplier must submit a new request.
- 9) The organization, and only the organization has the right to interpret the articles of this regulation, and all the beneficiaries of the application of this Regulation must be committed to interpretations issued by the organization.

Article (13) Transitional Provisions

- 1) The supplier is to take all the necessary corrective actions to conform the provisions of this Regulation, within a period of not more than (six months) from the date of working out.
- 2) While considering the provisions of paragraph (1) of this article, the supplier is allowed to circulate the products that are not fulfilling the requirements of this regulation, for a maximum one year period from the date of working out.
- 3) This Regulation - once adopted - cancels all preceding regulations issued in the field of conformity of cement, gypsum and their derived products as used in the sectors of construction and building for safety requirements before they are placed in the market and after the products are available.

Article (14) Publishing

These Regulations shall be published in the Official Gazette.

Annex (1)

A List of Polyethylene and Polypropylene Products Subject to this Regulation

| No. | Product Name | Custom Code |
|-----|---|--|
| 1 | Carrier Bags | 39211300 |
| 2 | Courier Bags and Parcels | 39211300 |
| 3 | Mail Order Bags for Periodicals (Bags for Magazines and Newspapers) | 39211300 |
| 4 | Plastic bags for soil treatment, agricultural/horticultural applications (e.g. banana bags and cultivated soil covers) | 39269069 |
| 5 | Bubble plastic bags and plastic covers for protection against shocks | 39211200 39211100 39202000 39219000 |
| 6 | Flower plastic wraps | 39211200 39211100 39202000 39219000 |
| 7 | Plastic covers for secondary packaging | 39211200 39211100 39202000 39219000 |
| 8 | Elastic plastic films 'rolls' for goods' packaging | 39211300 |
| 9 | Clinging plastic films 'rolls' for packaging | 39211300 |
| 10 | Plastic liners for cardboard boxes | 63063000 |
| 11 | Polyethylene sheets as table covers | 39211900 39232100 |
| 12 | Personal care products, made of plastics, such as gloves, shoe covers, and any disposable personal care plastic products | 39262090 39269099 63079040 |
| 13 | Bags for packaging of bread, nuts, sweets and all bakery products | 39232100 |
| 14 | Plastic bags for saplings | 39232100 |
| 15 | Heat-shrinkable plastic films 'rolls' | 39232100 |
| 16 | All plastic bags for one-time use, including shopping bags, garbage bags, clothes bags, one-time use food tools like plates, spoons and cups of food. | 39151000 39173210 39241090 39232100 39241039 |

Annex (2)
Standards List

| | Standard | Standard Title |
|----|-----------------------|---|
| 1 | SASO 2879 | Degradable Plastic Products |
| 2 | SASO ISO 14851:2009 | Determination of Ultimate Aerobic Biodegradability of Plastic Materials in an Aqueous Medium - Method of Measuring the Oxygen Demand in a Closed Respirometer |
| 3 | SASO ISO 14852:2009 | Determination of Ultimate Aerobic Biodegradability of Plastic Materials in an Aqueous Medium - Analysis of Evolved Carbon Dioxide Method |
| 4 | SASO ISO 14855-1:2014 | Determination of Ultimate Aerobic Biodegradability of Plastic Materials under Controlled Composting Conditions - Analysis of Evolved Carbon Dioxide Method - Part 1: General Method |
| 5 | SASO ISO 14855-2:2014 | Determination of the Aerobic Biodegradability Peak of Plastic Materials under Conditions of Fertilizers Degradation - Analysis of Evolved Carbon Dioxide Method - Part 2: Gravimetry of Carbon Dioxide in a Laboratory - Scale Test |
| 6 | SASO ISO 17556:2014 | Plastics - Determination of the Ultimate Aerobic Biodegradability in Soil by Measuring Oxygen Demand in a Respirometer or Measuring the Amount of Emitted Carbon Dioxide |
| 7 | ASTM D 6954 | Standard Guide for Detection of Degradable Plastics in Environment and Testing it through a Combination of Oxidation and Biodegradation |
| 8 | BS 8472:2011 | Methods of Evaluating the Biodegradability of Plastics Which Degrade by Oxidation then bio-degradability (OXO) and Evaluating the Plant Poisoning by Wastes in Secured Laboratory Conditions. |
| 9 | CEN/TR 15351 | Plastics - Vocabulary of Degradable Plastic Materials |
| 10 | 1863 SASO GSO | Food Packages - Part 2 Plastic Packages – General Requirements |
| 11 | ASTM D6988 | Standard Guide for Determining the Thickness of Test Specimens of Plastic Films |
| 12 | ASTM D5208-14 | Standard Practice for Fluorescent Ultraviolet (UV) Exposure of Photodegradable Plastics |
| 13 | ASTM D3826-98 :2013 | Standard Practice for Determining the Degradation End Point in the Degradation of Polyethylene and Polypropylene Using a Tensile Test |
| 14 | ASTM D4001 | Standard Test Method for Determination of Weight-Average Molecular Weight of Polymers |
| 15 | ASTM D2765-11 | Standard Test Methods for Determination of Gel Content and Swell Ratio of Cross-linked Ethylene Plastics |

| | | |
|----|----------------|--|
| 16 | ASTMD5988-12 | Standard Method for Determining Aerobic Biodegradation of Plastic Materials in Soil |
| 17 | ISO 17556:2012 | Plastics - Determination of the Ultimate Aerobic Biodegradation of Plastic Materials in Soil by Measuring Oxygen Demand in Measuring Respiration or the Amount of Emitted Carbon Dioxide |

Annex (3)

Conformity Assessment Form (Type 1a) according to ISO/IEC 17067

Type Approval

1/1 Type Approval

Type approval is defined as one of the conformity assessment procedures, where the notified body shall review the technical design of the product and check its validation, then acknowledge that the technical design of the product meets the requirements of the related Saudi technical regulations.

Type approval can be made via one of the following two ways:

- A)** Inspecting a typical sample of the full product, to be representing the expected production (production model)
- B)** Evaluating the technical design conformity of the product by reviewing the technical documentation and guides (design model), in addition to inspecting a representative sample of the proposed production (prototype), particularly for one or more of the parts that are more hazardous of the product (combining production model and design model)

1/2 Type Approval Procedures

1/1/2 Submitting an Application for Type Approval from a Notified Body

The manufacturer shall apply for type approval from a notified body of his choice; provided that the application includes the following:

- A)** Manufacturer's name and address
- B)** A written declaration that he did apply to any other notified body
- C)** Technical documents that enable evaluating the product's conformity with the requirements of Saudi technical regulations. These documents shall include proper analysis and evaluation of risks.
- D)** Technical documentation shall define the requirements applicable to the product; to include - as required by the evaluation - the design, manufacturing and operation (usage) requirements of the product.
- E)** The technical documents shall include the following items, as a minimum:
 - 1)** General description of the product
 - 2)** Design, manufacturing drawings and horizontal projections (diagrams) for the product elements, units, divisions and subdivisions, etc.
 - 3)** Any descriptions and explanations needed to understand the drawings, diagrams, and operation (usage) of the product.
 - 4)** List of fully or partially applicable Saudi standards or any other relevant technical specifications approved by SASO, in addition to a description of the solutions adopted to meet the essential requirements according to the Saudi technical

regulations, in case of not applying the standards listed. In case of partial use of Saudi standards, technical documentation shall clarify the applied items.

- 5) Design calculations reports, operations monitoring and testing reports, etc.
- 6) Test reports.
- 7) Representative samples of the proposed production. The notified body may request additional samples if needed.
- 8) Evidence supporting the appropriateness of the technical solutions adopted in the design, shall refer to all the documents followed, especially in case of the non-application of Saudi standards and/or the appropriate mentioned technical criteria. Supporting evidence shall include, when necessary, the results of tests performed in the laboratory at the manufacturer's discretion, or in another laboratory under his responsibility.

2/1/2 Tasks of the Notified Body

A) With respect to product

Study of the technical documentation and supporting evidences for the purpose of assessment of the technical design of the product.

B) With respect to samples

- 1) Ensure that the manufacturing of samples is in conformity with the technical documentation, in addition to identifying the designed elements in accordance with the Saudi standards, and those designed according to other specifications.
- 2) Performing the appropriate examinations and tests, either personally to through an agent to assure that the technical solutions adopted by the manufacturer meet the key requirements specified in standards, in case of non-application of relevant specifications.
- 3) Performing appropriate tests, or either personally or through an agent, to make sure, in the case of non-application of Saudi standards and/or other appropriate specifications, that the technical solutions adopted by the manufacturer meet the basic requirements of the Saudi technical regulations.

Defining the testing body in agreement with the manufacturer.

C) With respect to the Decisions of the Notified Body

- 1) The notified body shall issue an evaluation report of all actions carried out and its outputs. The notified body shall not publish the report in whole or in part without the manufacturer's approval.
- 2) If type is conforming with the requirements of Saudi technical regulations applied to the product in question, the notified body shall issue a type approval certificate for the manufacturer, It shall include the manufacturer's name and address, results of tests, terms of validity- if any-, the information necessary to determine the accredited type, and the certificate may also include related attachments.

- 3) The certificate, and its attachments, shall include all appropriate information needed to assess the conformity of products manufactured in accordance with the tested type and to make the surveillance during operation.
- 4) If type was found not conforming with the Saudi technical regulations' requirements applied to the product in question, the notified body shall not issue a type approval certificate, and it shall inform the applicant of its decision, accompanied with a detailed justification concerning the non-issuance of type approval certificate.
- 5) The notified body shall keep pace with all known technical developments, whenever these developments refer to non-conformity of the accredited type with the requirements of the Saudi technical regulations, then the notified body shall determine the need to perform additional testing, and inform the manufacturer in this case.
- 6) The manufacturer shall inform the notified body, that retains the technical documentation for the issued type approval certificate, with all the changes that may affect the product conformity of the attested type; according to the requirements of Saudi technical regulations. The manufacturer shall also inform the notified body with any changes to the terms of type approval certificate applicability, as such changes require further attesting on initial type approval certificate.
- 7) Each notified body shall inform SASO with type approval certificates and with any additions issued or certificates withdrawn. The notified body shall, on regular basis, or when required provide a list of type approval certificates and with any additions refused or with certificates suspended or restricted in any way.
- 8) Each notified body shall inform other notified bodies of type approval certificates and also any refused additions, and with additions suspended or restricted in any way. Also it shall be informed, when required, with type approval certificates or any issued additions.
- 9) When required, SASO and other notified bodies can obtain copies of type approval certificates and/or additions thereto. SASO can, when required, obtain copies of technical documentation and test results carried out by the notified body. The notified body shall keep a copy of type approval certificate, its attachments, and inserted additions in addition to the technical documents, including documents attached from the manufacturer until the certificate's expiry date.
- 10) Manufacturer shall keep a copy of type approval certificate, its attachments, and inserted additions thereto, in addition to the technical documents. Also, the manufacturer shall make all of these available to Regulatory Bodies and market survey authorities for 10 years after the product's placement in the market.
- 11) The supplier can submit the application mentioned in clause (2/1/1) above, and carry out pre-mentioned on behalf of the manufacturer, provided that the manufacturer gives his consent.

Annex (4)

Supplier Conformity Declaration Form

This form shall be filled in on the company's letterhead papers

Supplier Conformity Declaration

1) Supplier Details:

Address:

Contact Person:

Email: -----

Tel. No.: -----

Fax No. -----

2) Product Details

Trademark:

Type:

Description:

Level:

Category:

Reference Standards / Technical Specifications

We, hereby, acknowledge that the above-mentioned product is conforming with the Saudi technical regulation (), and the Saudi standards included therein.

The competent person:

Company Name:

Signature:

Date:

Annex (5) Test Reporting

The report shall identify the following:

- 1) Product use and purpose of application in a clear statement.
- 2) Product specifications (characteristics) including its thickness.
- 3) Polymer type.
- 4) The required storage conditions that maintains the properties of plastics and that prevent premature biodegradation, in addition to clearly stating the shelf-life.
- 5) There shall be information on shipment tracking, terms of shipment and transportation, and the required level of humidity and temperature.
- 6) Stating the anticipated storage and operation periods.
- 7) Recording the conditions of exposure concerning temperature, timing, moisture and oxygen.
- 8) Recording the conditions of and time of exposure to radiation ($\text{kJ/m}^2 \cdot \text{nm}$ at 340 nm), if used.
- 9) Reporting each of the molecular weight, tensile elongation and percentage of gel materials in samples before and after the indicated time for abiotic test exposure.
- 10) The mass before and after the test shall be reported.
- 11) The extent of biodegradation, expressed in a percentage of theoretical carbon dioxide, shall be reported.
- 12) The percentage of gel or other non-degradable components, shall be assigned.
- 13) Volatile materials produced by the oxidation process (carbon dioxide) shall be specified.
- 14) Metal concentrations specified in table (1) below shall be announced.
- 15) Stating the type, amount and source of recycled materials used in the final product, if any.

Note: Additives can have a very significant effect on the performance of the oxo-biodegradable additions system. Stabilizers, such as antioxidants or UV absorbers in the substrate film, can slow down the degradation response while certain types of pigments can accelerate degradation.

Table (1) The maximum allowed metal concentrations in mg/kg of dry material

| Element | mg/kg of dry material | Element | mg/kg of dry material |
|---------|-----------------------|---------|-----------------------|
| Zn | 150 | Cr | 50 |
| Cu | 50 | Mo | 1 |
| Ni | 25 | Se | 0.75 |
| Cd | 0.5 | As | 5 |
| Pb | 50 | F | 100 |

Test Report Form

| Report on materials test according to KSA standard | | | |
|--|--|-----------------------------|--|
| Date of report: | | Date of reporting issuance | |
| Name of the manufacturer and / or the trademark | | Test laboratory | |
| Sample submitting entity 1- Target application 2- Plastic type 3- Production date 4- The shelf life period | | No. of testing report pages | |
| Sample masses (mg) | | | |
| Sample sizes (mm) | | | |
| Tested | Abiotic degradation test | | |
| Test used | Results | Reference standard | |
| Exposure cycle A) and total exposure time Lamp UV used, humidity/ Temperature | | | |
| 1- M.wt | | | |
| 2- Tensile strength | | | |
| 3- Gel content | | | |
| 2- Elongation and strength | | | |
| 3- Gel content | | | |
| Biotic test | Biotic test report attached | | |
| Plant – toxicity | Plant - toxicity test, report attached according to 5/6 of SASO 2879 | | |
| metals concentration | metals test report attached according to 5/1/4 of SASO 2879 | | |
| Product fit to its standard | The test report attached as per each product standard reporting requirements | | |

Annex (6) Logo Design



لون البلاستيك = أسود
عدد ألوان الطباعة = لون واحد



لون البلاستيك = أبيض
عدد ألوان الطباعة = لون واحد



لون البلاستيك = متعدد
عدد ألوان الطباعة = لون واحد