
L.N. 433 of 2010

**PRODUCT SAFETY ACT
(CAP. 427)**

**Framework for the Setting of Ecodesign Requirements for
Energy-Using Products (Amendment) (No.2) Regulations, 2010**

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, the Prime Minister, on the advice of the Malta Standards Authority, has made the following regulations:-

1. (1) The title of these regulations is the Framework for the Setting of Ecodesign Requirements for Energy-Using Products (Amendment) (No.2) Regulations, 2010 and they shall be read and construed as one with Framework for the Setting of Ecodesign Requirements for Energy-Using Products Regulations, 2007 hereinafter referred to as “the principal regulations”. Citation and scope
L.N. 347 of 2007.

(2) These regulations implement the requirements of Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of eco design requirements for energy related products.

2. Regulation 1 of the principle regulations shall be amended as: Amends regulation
1 of the principal
regulations.

a) for sub-regulation (1) thereof, for the words “Energy-Using” in the title to the principle regulations, there shall be substituted the words “Energy-Related”;

b) for sub-regulation (2) thereof , there shall be substituted the following:

“(2) These regulations implements to the requirements of Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009

establishing a framework for the setting of eco design requirements for energy related products, hereinafter referred to as “the Directive.””;

c) sub-regulation (7) thereof shall be deleted; and

d) immediately after sub-regulation (5) thereof, shall be added the following:

“(6) The Directorate shall be the competent authority as regards Articles 3(4), 7(7) and 13(3) of the Directive.”.

Amends-regulation
2 of the principal
regulations.

3. In sub-regulation (1) of regulation 2 of the principal regulations, for the words “energy using products” shall there be substituted with the words “energy related products”.

Amends regulation
3 of the principal
regulations.

4. Regulation 3 of the principal regulations shall be amended as follows:

a) For the definition “energy using product” there shall be substituted the following:

“ “energy-related product”, herein after referred to as a ”product”, means any good that has an impact on energy consumption during use which is placed on the market and, or put into service, and includes parts intended to be incorporated into energy-related products covered by this Directive which are placed on the market and, or put into service as individual parts for end-users and of which the environmental performance can be assessed independently;”;

b) for the definition “manufacturer” there shall be substituted the following:

“ “manufacturer” means the natural or legal person who manufactures products covered by these regulations and is responsible for their conformity with these regulations in view of their being placed on the market or put into service under the manufacturer’s own name or trademark or for the manufacturer’s own use. In the absence of a manufacturer as defined herein or of an importer as defined in this regulation, any natural or legal person who places on the market and, or puts into

service products covered by these regulations shall be considered a manufacturer;” and

c) for the definition of “recovery” there shall be substituted by the following:

“ “recovery” means any of the applicable operations provided for in Annex II B to Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste¹;

5. In regulations 3, 4, 5, 6, 7, 8, and 10 and in Schedule II of the principal regulations, for the words “energy using product” there shall be substituted the word “product” and for the words “energy using products” there shall be substituted the word “products” wherever they occur.

General amendment of regulations 3 to 8 and 10 and Schedule II of the principal regulations.

6. Sub-regulation (5) of regulation 4 shall be substituted as follows:

Amends regulation 4 of the principal regulations.

“(5) Where the manufacturer is not established in the Community and in the absence of an authorised representative, the importer shall have the following obligations –

(a) to ensure that the product placed on the market and, or put into service complies with this Directive and the applicable implementing measure; and

(b) to keep and make available the EC declaration of conformity and the technical documentation.”.

7. In sub-regulations (1) and (3) of regulation 5 of the principal regulations, for the words “declaration of conformity” wherever they occur, there shall be substituted the words “EC type declaration of conformity”.

Amends regulation 5 of the principal regulations.

8. Sub-regulation (2) of regulation 6 of the principal regulations shall be substituted as follows:

Amends regulation 6 of the principal regulations.

“(2) (a) The conformity assessment procedures shall be specified by the corresponding implementing measures.

¹O.J L 396. 30-12-2006, p1

(b) Implementing measures may refer to the following conformity assessment modules:

(i) the internal design control set out in Schedule IV, and the management system set out in Schedule V; or

(ii) or a module described in Annex II to Decision 768/2008/EC².

(c) Where the Director of Market Surveillance has strong indications of probable non-compliance of a product, he shall immediately inform the Directorate who shall as soon as possible publish a substantiated assessment of the product's compliance which may be conducted by a notified body, in order to allow, if appropriate, timely corrective action, if any.

(d) Where a product covered by implementing measures is designed by an organisation registered in accordance with Regulation (EC) No. 761/2001 of the European Parliament and of the Council of 19th March 2001 allowing voluntary participation by organisations in a Community Eco Management and Audit Scheme (EMAS)³ and the design function is included within the scope of that registration, the management system of that organisation shall be presumed to comply with the requirements of Schedule V.

(e) If a product covered by implementing measures is designed by an organisation having a management system which includes the product design function and which is implemented in accordance with harmonised standards the reference numbers of which have been published in the OJ, that management system shall be presumed to comply with the corresponding requirements of Schedule V.”.

(3) In sub-regulation 6(4) of the principal regulations the word “Community” shall be substituted by the words “institutions of the European Union”

Adds new regulation 12 to the principal regulations.

9. Immediately after regulation 11 of the principal regulations there shall be added the following new regulation:

²O.J. No. L 218, 13-08-2008, p 82

³O.J. No. L 114, 24-04-2001, p 1

“Penalties 12. The penalties as provided by the Product Safety Act shall apply in respect of the infringement of these regulations.”

11. Schedule I to the principal regulations shall be substituted as follows:

Substitutes Schedule I to the principal regulations.

“ Schedule I

Based on Annex I of the Directive

METHOD FOR SETTING GENERIC ECODESIGN REQUIREMENTS

(Referred to in regulations 4 and 9 to these regulations)

Generic ecodesign requirements aim at improving the environmental performance of products, focusing on significant environmental aspects thereof without setting limit values. The method referred to in this Schedule must be applied when it is not appropriate to set limit values for the product group under examination. The Commission must, when preparing a draft implementing measure to be submitted to the Committee referred to in Article 19(1) of the Directive, identify significant environmental aspects which must be specified in the implementing measure.

In preparing implementing measures laying down generic ecodesign requirements pursuant to Article 15 of the Directive and Schedule I to these regulations, the Commission must identify, as appropriate to the product covered by the implementing measure, the relevant ecodesign parameters from among those listed in Part 1, the information supply requirements from among those listed in Part 2 and the requirements for the manufacturer listed in Part 3.

Part 1. Ecodesign parameters for energy-using products

1.1. In so far as they relate to product design, significant environmental aspects must be identified with reference to the following phases of the lifecycle of the product:

- (a) raw material selection and use;
- (b) manufacturing;
- (c) packaging, transport, and distribution;

(d) installation and maintenance;

(e) use; and

(f) end of life, meaning the state of a product having reached the end of its first use until its final disposal.

1.2. For each phase, the following environmental aspects must be assessed where relevant:

(a) predicted consumption of materials, of energy and of other resources such as fresh water;

(b) anticipated emissions to air, water or soil;

(c) anticipated pollution through physical effects such as noise, vibration, radiation, electromagnetic fields;

(d) expected generation of waste material; and

(e) possibilities for reuse, recycling and recovery of materials and/or of energy, taking into account Directive 2002/96/EC⁴.

1.3. In particular, the following parameters must be used, as appropriate, and supplemented by others, where necessary, for evaluating the potential for improving the environmental aspects referred to in point 1.2:

(a) weight and volume of the product;

(b) use of materials issued from recycling activities;

(c) consumption of energy, water and other resources throughout the life cycle;

(d) use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC of 27th June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances⁵ and taking into account legislation on the marketing and use

⁴O.J. No. L 218, 13-08-2008, p 82

⁵O.J. No. L 114, 24-04-2001, p 1

of specific substances, such as Council Directives 76/769/EEC⁶ of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations or Directive 2002/95/EC⁷;

(e) quantity and nature of consumables needed for proper use and maintenance;

(f) ease for reuse and recycling as expressed through: number of materials and components used, use of standard components, time necessary for disassembly, complexity of tools necessary for disassembly, use of component and material coding standards for the identification of components and materials suitable for reuse and recycling (including marking of plastic parts in accordance with ISO standards), use of easily recyclable materials, easy access to valuable and other recyclable components and materials; easy access to components and materials containing hazardous substances;

(g) incorporation of used components;

(h) avoidance of technical solutions detrimental to reuse and recycling of components and whole appliances;

(i) extension of lifetime as expressed through: minimum guaranteed lifetime, minimum time for availability of spare parts, modularity, upgradeability, reparability;

(j) amounts of waste generated and amounts of hazardous waste generated;

(k) emissions to air (greenhouse gases, acidifying agents, volatile organic compounds, ozone depleting substances, persistent organic pollutants, heavy metals, fine particulate and suspended particulate matter) without prejudice to Directive 97/68/EC of the European Parliament and of the Council of 16th December 1997 relating to

⁶OJ No. L262, 27-09-1976, p. 201-203.

⁷OJ No. L037, 13-02-2003, p. 19-23.

measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non road mobile machinery⁸;

(l) emissions to water (heavy metals, substances with an adverse effect on the oxygen balance, persistent organic pollutants); and

(m) emissions to soil (especially leakage and spills of dangerous substances during the use phase of the product, and the potential for leaching upon its disposal as waste).

Part 2. Requirements relating to the supply of information

Implementing measures may require information to be supplied by the manufacturer that may influence the way the product is handled, used or recycled by parties other than the manufacturer. This information may include, where applicable:

(a) information from the designer relating to the manufacturing process;

(b) information for consumers on the significant environmental characteristics and performance of a product, accompanying the product when it is placed on the market to allow consumers to compare these aspects of the products;

(c) information for consumers on how to install, use and maintain the product in order to minimise its impact on the environment and to ensure optimal life expectancy, as well as on how to return the product at end of life, and, where appropriate, information on the period of availability of spare parts and the possibilities of upgrading products; and

(d) information for treatment facilities concerning disassembly, recycling, or disposal at end of life.

Information should be given on the product itself wherever possible.

This information must take into account the obligations under the other Community legislation, such as Directive 2002/96/EC.

⁸OJ No. L59, 27-02-1998, p. 1. Directive as last amended by Directive 2004/26/EC (OJ NO. L146, 30-04-2004, p. 1).

Part 3. Requirements for the manufacturer

1. Addressing the environmental aspects identified in the implementing measure as capable of being influenced in a substantial manner through product design, manufacturers of products must perform an assessment of the product model throughout its lifecycle, based upon realistic assumptions about normal conditions and purposes of use. Other environmental aspects may be examined on a voluntary basis.

On the basis of this assessment manufacturers will establish the product's ecological profile. It will be based on environmentally relevant product characteristics and inputs/outputs throughout the product life cycle expressed in physical quantities that can be measured.

2. Manufacturers must make use of this assessment to evaluate alternative design solutions and the achieved environmental performance of the product against benchmarks.

The benchmarks must be identified by the Commission in the implementing measure on the basis of information gathered during the preparation of the measure.

The choice of a specific design solution will achieve a reasonable balance between the various environmental aspects and between environmental aspects and other relevant considerations, such as safety and health, technical requirements for functionality, quality, and performance, and economic aspects, including manufacturing costs and marketability, while complying with all relevant legislation.”.

11. Schedule IV to the principal regulations shall be substituted as follows :

Substitutes Schedule IV to the principal regulations.

“ Schedule IV

Based on Annex IV of the Directive

INTERNAL DESIGN CONTROL

(Referred to in regulation 6 of these regulations)

1. This Schedule describes the procedure whereby the manufacturer or its authorised representative who carries out

the obligations laid down in section 2 of this Schedule ensures and declares that the product satisfies the relevant requirements of the applicable implementing measure. The declaration of conformity may cover one or more products and must be kept by the manufacturer.

2. A technical documentation file making possible an assessment of the conformity of the product with the requirements of the applicable implementing measure will be compiled by the manufacturer.

The documentation must contain, in particular:

- (a) a general description of the and of its intended use;
- (b) the results of relevant environmental assessment studies carried out by the manufacturer, and/or references to environmental assessment literature or case studies, which are used by the manufacturer in evaluating, documenting and determining product design solutions;
- (c) the ecological profile, where required by the implementing measure;
- (d) elements of the product design specification relating to environmental design aspects of the product;
- (e) a list of the appropriate standards referred to in regulation 7.(2) of these regulations, applied in full or in part, and a description of the solutions adopted to meet the requirements of the applicable implementing measure where the standards referred to in regulation 7.(2) of these regulations have not been applied or where those standards do not cover entirely the requirements of the applicable implementing measure;
- (f) a copy of the information concerning the environmental design aspects of the product provided in accordance with the requirements specified in Annex I, Part 2 of the Directive, which is set out in Schedule I, Part 2 to these regulations; and
- (g) the results of measurements on the ecodesign requirements carried out, including details of the conformity

of these measurements as compared with the ecodesign requirements set out in the applicable implementing measure.

3. The manufacturer must take all measures necessary to ensure that the product will be manufactured in compliance with the design specifications referred to in section 2 and with the requirements of the measure which apply to it.”.

12. Schedule V to the principal regulations shall be substituted as follows:

Substitutes Schedule V to the principal regulations.

“ Schedule V

Based on Annex V of the Directive

MANAGEMENT SYSTEM FOR ASSESSING CONFORMITY

(Referred to in regulation 6 of these regulations)

1. This Schedule describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this Schedule ensures and declares that the product satisfies the requirements of the applicable implementing measure. The declaration of conformity may cover one or more products and must be kept by the manufacturer.

2. A management system may be used for the conformity assessment of a product provided that the manufacturer implements the environmental elements specified in section 3 of this Schedule.

3. Environmental elements of the management system

This section specifies the elements of a management system and the procedures by which the manufacturer can demonstrate that the complies with the requirements of the applicable implementing measure.

3.1. The environmental product performance policy

The manufacturer must be able to demonstrate conformity with the requirements of the applicable implementing measure. The manufacturer must also be able to provide a framework for setting and reviewing environmental product performance

objectives and indicators with a view to improving the overall environmental product performance.

All the measures adopted by the manufacturer to improve the overall environmental performance of and to establish the ecological profile of a product, if required by the implementing measure, through design and manufacturing, must be documented in a systematic and orderly manner in the form of written procedures and instructions.

These procedures and instructions must contain, in particular, an adequate description of:

(a) the list of documents that must be prepared to demonstrate the product's conformity, and, if relevant, that have to be made available;

(b) the environmental product performance objectives and indicators and the organisational structure, responsibilities, powers of the management and allocation of resources with regard to their implementation and maintenance;

(c) the checks and tests to be carried out after manufacture to verify product performance against environmental performance indicators;

(d) the procedures for controlling the required documentation and ensuring that it is kept up to date; and

(e) the method of verifying the implementation and effectiveness of the environmental elements of the management system.

3.2. Planning

The manufacturer must establish and maintain

(a) procedures for establishing the ecological profile of the product;

(b) environmental product performance objectives and indicators, which consider technological options taking into account technical options and economic requirements; and

- (c) a programme for achieving these objectives.

3.3. Implementation and documentation

3.3.1. The documentation concerning the management system must in particular, comply with the following:

- (a) responsibilities and authorities will be defined and documented in order to ensure effective environmental product performance and reporting on its operation for review and improvement;

- (b) documents must be established indicating the design control and verification techniques implemented and processes and systematic measures used when designing the product; and

- (c) the manufacturer must establish and maintain information to describe the core environmental elements of the management system and the procedures for controlling all documents required.

3.3.2. The documentation concerning the must contain, in particular:

- (a) a general description of the product and of its intended use;

- (b) the results of relevant environmental assessment studies carried out by the manufacturer, and/or references to environmental assessment literature or case studies, which are used by the manufacturer in evaluating, documenting and determining product design solutions;

- (c) the ecological profile, where required by the implementing measure;

- (d) documents describing the results of measurements on the ecodesign requirements carried out including details of the conformity of these measurements as compared with the ecodesign requirements set out in the applicable implementing measure;

- (e) the manufacturer must establish specifications indicating, in particular, standards which have been applied;

where standards referred to in regulation 8.(5) of these regulations are not applied or where they do not cover entirely the requirements of the relevant implementing measure, the means used to ensure compliance; and

(f) a copy of the information concerning the environmental design aspects of the product provided in accordance with the requirements specified in Annex I, Part 2 of the Directive, which is set out in Schedule I, Part 2 to these regulations.

3.4. Checking and corrective action

3.4.1 The manufacturer must:

(a) take all measures necessary to ensure that the product is manufactured in compliance with its design specification and with the requirements of the implementing measure which applies to it;

(b) establish and maintain procedures to investigate and respond to non conformity, and implement changes in the documented procedures resulting from corrective action; and

(c) carry out at least every three years a full internal audit of the management system with regard to its environmental elements.”.