Draft 1

23 July, 2022

Manufacturers' key legal obligations when placing a household appliance on the EU market

(The Magenta Guide of APPLiA Hungary to its members)

July, 2022

1. Forewords

This guide aims at summarising the key principles and identifying the key pieces of legislations applicable to household appliances when they are placed on the EU market.

2. Introduction

When we talk about rules applicable to products being placed on the EU market, we have to focus on three main types of instruments:

- → directives;
- → regulations; and
- → harmonised standards.

What should we know about them?

The main difference between a directive and a regulation is, that the **directives** are addressed to EU Member States, and they must be transposed into national laws (they do not have direct effects), while the **regulations** have direct effects, they do not need transposition. Therefore in case of directives market actors always have to check the EU Member States' local legislations that transposing the directive into the national law.

(However, in certain cases, the Court recognises the direct effect of directives, too, in order to protect the rights of individuals. A directive has direct effect when its provisions are unconditional and sufficiently clear and precise and when the EU Member State has not transposed the directive by the deadline. However, it can only have direct vertical effect, which means that only individuals can refer to this direct effect in court cases against EU Member States.)

There is, however, a tendency that is worth mentioning: the EU lawmaking is currently moving into the direction of replacing existing directives with regulations. In case of the energy label a framework regulation has already replaced the earlier framework directive, we are now in the course of a similar procedure in case of the new Batteries Regulation, and we already know that the existing General Product Safety and the Ecodesign Directive will also be replaced with a new regulations. Furthermore, it is very possible that the WEEE Directive will be amended as a regulation in the near future. Such a trend will result in better harmonisation of EU legislations.

As far as **harmonised standards** are concerned, they are – as we will see later – only voluntary applications, providing manufacturers with possible technical solutions.

If we take into consideration all the relevant legislations applicable to products being put on the EU market, we can easily end up in a chaos. Therefore, before listing the key pieces of legislations, it is advised to understand the stucture, levels and thematic types of the EU rules.

The two main groups of applicable legislations we need to focus on are:

→ the harmonised product legislations (the main guide to them is the Blue Guide 2022; and
→ consumer legislations.

There are also some further legislations of concern (this guide contains a list of such legislation in section 5).

Harmonised product legislations

On the basis of manufacturers' obligations, the following key thematic types of rules can be identified:

(i) GPSD – General Product Safety Directive

It applies to products in general, if there is no special law applicable.

(ii) Substance restrictions

REACH, RoHS, SCIP, food contact materials, F-gas etc.

(iii) Laboratory testing requirements

This is the basis of the declaration of conformity.

(iv) Document requirements

Declaration of conformity and the technical documentation.

(v) Labelling requirements

CE marking, WEEE, energy labels, F-gas etc.

(vi) Standards

Consumer legislations

Consumer legislations covers a huge number of legislations that is constantly growing, due to the growing importance of e-commerce and digitalisation. Therefore in this Magenta Guide we will focus on the most important pieces of this territory of product legislations:

→ the new Consumer Agenda of the EU and the new Consumer Rights Directive;
→ the new Sales of Goods Directive; and
→ the E-commerce Directive.

3. The harmonised product legislations

The key and very detailed guide to the harmonised product legislations is the Blue Guide 2022.

In this section 3. this Magenta Guide will also follow the information of the Blue Guide 2022.

3.1 The history of the EU product legislation

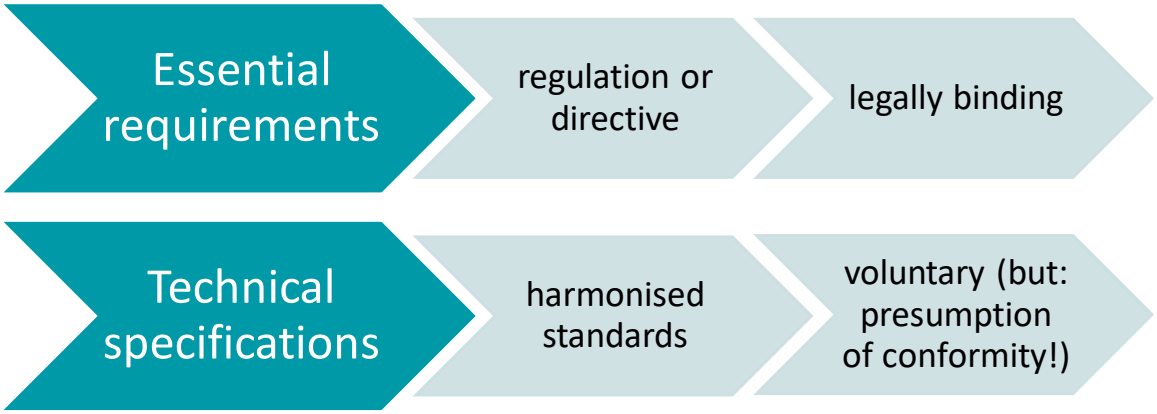
The history of the EU product legislation follows 5 key phases:

1. Old Approach	Detailed legal text with all technical and administrative obligations
2. New Approach (1985)	Essential requirements in the legal text, and technical details in standards (the birth of standardisation)
3. Conformity assessment	Required by the various harmonisation acts
4. New Legislative Framework (2008)	All elements for conformity assessment (incl. accreditation and market surveillance) are developed
5. New Regulations (2019)	on (i) market surveillance and (ii) mutual recognition of goods

3.2 The New Approach and the New Legislative Framework

The New Approach and the New Legislative Framework:

- → harmonisation of EU rules
- → to the extent of **essential requirements** (this covers the result or hazard, but not the technical solution for doing so)
- → **technical specifications** must be laid down in harmonised standards – they are voluntary applications, possible technical solutions to the legally binding essential requirements
- → products produced in compliance with the harmonised standards will benefit from the **presumption of conformity**



A **harmonised standard** is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

If manufacturers choose not to apply harmonised standards, they have the obligation to demonstrate that their products are in conformity with essential requirements by the use of other means of their own choice that provide for the level of safety or protection of other interests required by the applicable legislation. These can be other standards such as national standards, international standards, European standards etc. In these cases the manufacturers do not benefit from the presumption of conformity, but have to demonstrate the conformity themselves. This implies that they demonstrate, in the technical file of a relevant product, in a more detailed manner how the standards or technical specifications they use provide conformity with the essential requirements, for instance by carrying out a more in-depth risk assessment on the product, a gap analysis, etc.

The New Legislative Framework:

- → essential or other legal requirements;
- → product standards;
- → standards and rules for the competence of conformity assessment bodies as well as for accreditation;
- → standards for quality management;
- → conformity assessment procedures;
- → CE marking, accreditation policy; and
- → market surveillance policy including the control of products from third countries.

Applicable legislations:

Regulation (EU) 1025/2012 on standardisation (click)

Regulation (EC) 765/2008 on accreditation and CE marking (click)

Regulation (EU) 2019/1020 on market surveillance and compliance of products (click)

3.3 Mutual Recognition of Goods

Products lawfully marketed in one EU Member State should in principle move freely throughout the EU. In the absence of EU harmonisation legislation, EU Member States are free to legislate on their territory subject to the EU Treaty rules on free movement of goods (Arts. 34 – 36).

Barriers to free movement of goods which result from differences in national legislation may only be accepted if

- → the national rule of the EU Member State of destination pursues a legitimate public interest objective; and
- → the measure restricting or denying access is proportionate, meaning that the measure is appropriate for securing the attainment of the objective and necessary (it does not go beyond what is necessary for attaining the objective).

Applicable legislation:

Regulation (EU) 2019/515 on mutual recognition of goods (click)

3.4 The General Product Safety Directive (GPSD)

The GPSD is intended to ensure product safety throughout the EU for all non-food consumer products to the extent that they are not covered by sector-specific EU harmonisation legislation. The GPSD has set up the EU Rapid Alert System which is used to quickly exchange information between Member States and the Commission on measures taken against dangerous non-food products (RAPEX).

On 30 June 2021, the Commission adopted a proposal for a new General Product Safety Regulation, to replace the GPSD. (Click here for the latest news on this activity.)

Appliacable legislation:

Directive 2001/95/EC of general safety of products (click)

3.5 The new market surveillance regulation

Regulation (EU) 2019/1020 on market surveillance and compliance of products entered into force on 16 July, 2021 (MS regulation).

The MS regulation provides:

- → clear and uniform rules applying to non-food products and economic operators;
- → requirements (infrastructure, organisation, legal powers, etc.) to ensure that market surveillance can cope with enforcing EU legislation;
- → streamlined market surveillance procedures for controlling products within the EU and at its borders (import controls);
- → tools to coordinate activities carried out by national surveillance bodies across the EU (e.g. discussion forums, IT databases, and common market surveillance campaigns).

The MS regulation is a very important piece of legislation, because:

- → it identifies the various market actors and their obligations (ie. manufacturer, distributor, authorised representative, importer etc.); and
- → its Annex I. lists all the specific EU harmonisation legislations (ie. WEEE, F-gas, energy label, ecodesign etc.).

The Blue Guide 2022 provides detailed explanation to the terms and definition of the MS regulation.

The EU harmonisation legislation applies:

- → when the product is placed on the EU market and to any subsequent operation which constitutes making available until it reaches the end-user.

- → to all forms of selling. A product offered in a catalogue or by means of electronic commerce has to comply with EU harmonisation legislation when the catalogue or website directs its offer to the EU market and includes an ordering and shipping system.

- → to newly manufactured products but also to used and second-hand products imported from a third country when they enter the EU market for the first time

- → to finished products as defined by the scope of each legislation.

(A product which has been subject to important changes or overhauls aiming to modify its original performance, purpose or type may be considered as a new product. The person who carries out the changes becomes then the manufacturer with the corresponding obligations.)

The territorial scope of the harmonised legislations:

- → EU harmonisation legislation applies to the Member States of the EU and to certain European territories to the extent necessary to give effect to the arrangements set out in the Accession Treaty of the relevant Member States.

- → The Agreement on the European Economic Area is established between the European Union and Iceland, Liechtenstein and Norway. The Agreement extends the internal market to these three EFTA States – commonly known as EEA EFTA States.

- → The Customs Union Agreement between the EU and Turkey aims to ensure the free movement of products between the EU and Turkey, by eliminating import controls at the EU-Turkey border on such products.

- → The Protocol on Ireland and Northern Ireland of the Agreement on the Withdrawal of the UK from the EU extends also the application of certain Union product legislation to Northern Ireland.

3.6 Product requirements under the harmonisation legislations

3.6.1 The traceability requirements

The traceability requirements allow tracing the history of the product and support market surveillance. It allows market surveillance authorities to find the liable economic operators and obtain evidence of the product compliance. They include **labelling the product** and **identifying the economic operators** in the distribution chain.

3.6.2 The technical documentation and the Declaration of Conformity

The manufacturer must draw up a **technical documentation**. The technical documentation is intended to provide information on the design, manufacture and operation of the product.

The contents of the technical documentation are laid down, in each Union harmonisation act, in accordance with the products concerned.

The technical documentation must be written in a language accepted by the notified body.

The manufacturer or the authorised representative established within the EU must draw up and sign a **Declaration of Conformity** as part of the conformity assessment procedure provided for in the EU harmonisation legislation.

The Declaration of Conformity must contain all relevant information to identify the EU harmonisation legislation according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other technical specifications.

A single declaration of conformity is required whenever a product is covered by several pieces of EU harmonisation legislation requiring a Declaration of Conformity.

The single declaration of conformity can be made up of a dossier containing all relevant individual declarations of conformity.

The Declaration of Conformity must be written in a language required by the EU Member States.

The **technical documentation** and the **Declaration of Conformity** must be kept for 10 years from the date of placing the product on the market, unless the applicable Union harmonisation legislation expressly provides for any other duration.

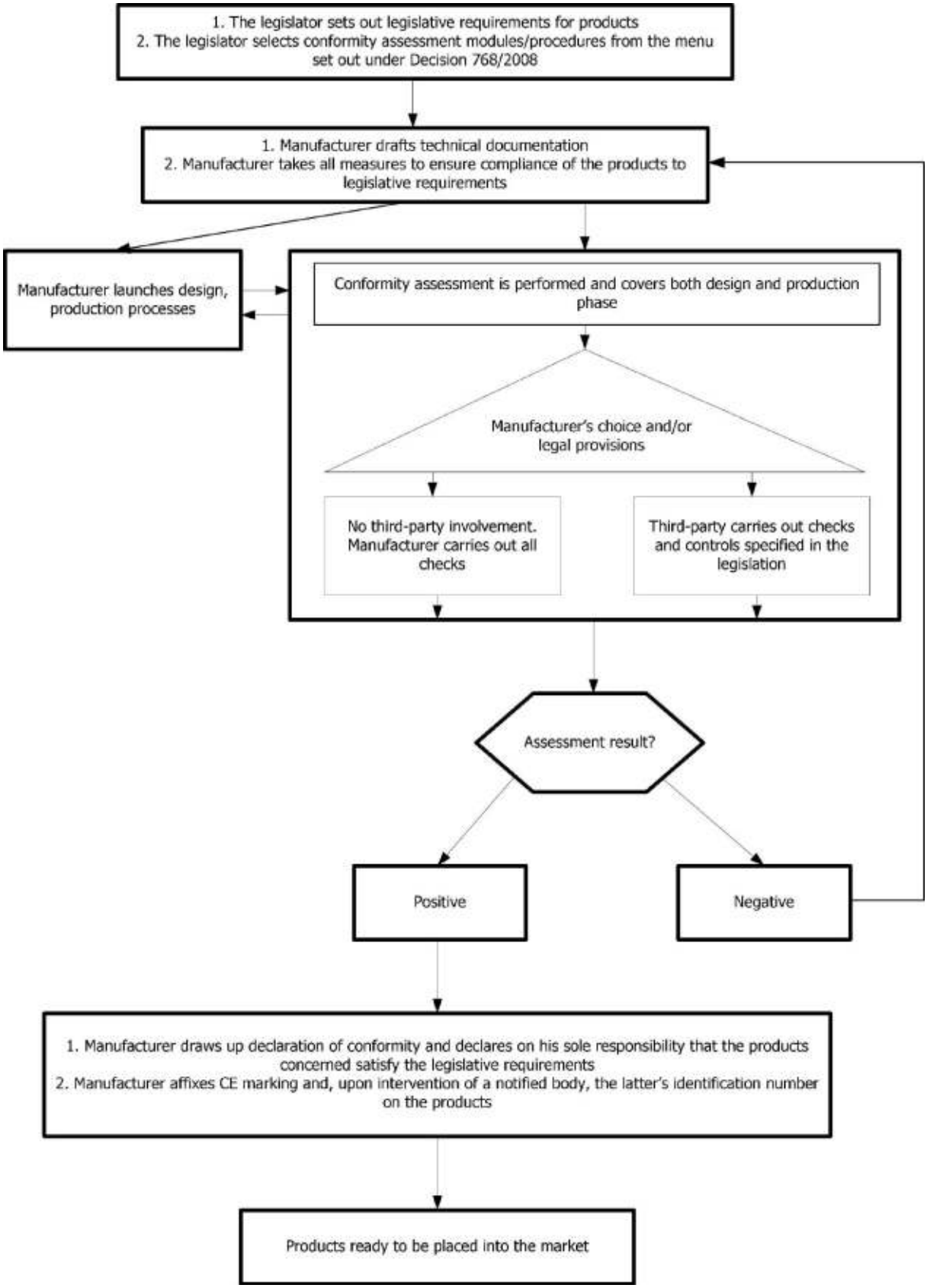
3.6.3 The CE marking

The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking.

The CE marking is affixed on products that will be placed on the EEA and Turkish market, whether they are manufactured in the EEA, in Turkey or in another country.

3.6.4 The conformity assessment

The following chart of the Blue Guide 2022 shows the steps of the conformity assessment:


1. The legislator sets out legislative requirements for products
2. The legislator selects conformity assessment modules/procedures from the menu set out under Decision 768/2008
1. Manufacturer drafts technical documentation
2. Manufacturer takes all measures to ensure compliance of the products to legislative requirements
Manufacturer launches design, production processes
Conformity assessment is performed and covers both design and production phase
Manufacturer's choice and/or legal provisions
No third-party involvement. Manufacturer carries out all checks
Third-party carries out checks and controls specified in the legislation
Assessment result?
Positive
Negative
1. Manufacturer draws up declaration of conformity and declares on his sole responsibility that the products concerned satisfy the legislative requirements
2. Manufacturer affixes CE marking and, upon intervention of a notified body, the latter's identification number on the products
Products ready to be placed into the market

Applicable legislations:

Regulation (EC) 765/2008 on accreditation and CE marking (click)

Regulation (EU) 2019/1020 on market surveillance and compliance of products (click)

4. Consumer legislations

The EU Commission published a New Consumer Agenda on 13 November, 2020. Its aims are the followings:

- → tackle the new challenges to consumer rights and opportunities for consumer empowerment brought about by the green and digital transitions, the COVID pandemic and the plans for post-COVID recovery;
- → protect vulnerable consumers more effectively in the new economic realities of the COVID-19 crisis and its likely aftermath; and
- → address the growing importance of international cooperation and effective enforcement in ensuring consumer rights in the globalisation era.

The key element of the New Consumer Agenda is a new Consumer Rights Directive (CRD) (Directive (EU) 2019/2161), that is replacing 4 earlier directives.

A detailed CRD Guide gives explanation on:

- → interplay with other EU legislation;
- → contracts where the consumer provides personal data;
- → obligations of online marketplaces;
- → transparency of search results;
- → personalised price;
- → consumer's right of withdrawal from contracts concluded during unsolicited visits or excursions;
- → consumer's right of withdrawal from contracts for online digital content;
- → consequences of trader's failure to inform about the right of withdrawal;
- → enforcement and penalties.

As far as product are concerned, we cannot forget about the new **Sales of Goods Directive** (Directive (EU) 2019/771), that entered into force on 1 January, 2022. This new directive regulates the key rules on the legal and commercial guarantees, including now the rules on digital contents (software update obligation!).

It must be highlighted, that even if this directive suggests a two-year legal guarantee tools to adopt be EU Member States, this legal instrument variest to a large scale all over the EU.

It is also important to note, that this directive will be amended in the near future in accordance with the Right to Repair initiative.

Detailed legal interpretation of the Sales of Goods directive is available here.

The **E-commerce Directive** is the foundational legal framework for online services in the EU. It aims to remove obstacles to cross-border online services.

The EU is focused on defining an appropriate e-commerce framework and preventing unfair discrimination against consumers and businesses who access content or buy goods and services online within the EU.

Examples of services covered by the E-commerc Directive include:

- → online information services;
- → online selling of products and services;
- → online advertising;
- → professional services; and
- → entertainment services and basic intermediary services, including services provided free of charge to the recipient, such as those funded by advertising.

Upcoming legislations that will very likely touch future product related obligations of manufacturers:

- → Data Act
- → Digital Services Act package

Applicable legislations:

Directive (EU) 2019/2161 on consumer protection (click)

Directive (EU) 2019/771 on the sales of goods (click)

Directive 2000/31/EC on e-commerce (click)

5. Other important legislations

Legislations connected to the production phase:

- → Food Contact Materials Regulation (for more info)
- → Drinking Water Directive

Legislations connected to the end-of-life phase:

- → Waste Framework Directive (WFD)
- → SCIP database (on the basis of the WFD)

Applicable legislations:

Regulation (EC) 1935/2004 on food contact materials (click)

Directive 98/2008/EC on waste (Waste Framework Directive) (click)

Directive 98/83/EC on drinking water (click)

Annex

List of applicable legislations mentioned in this Magenta Guide:

1. Regulation (EU) 1025/2012 on standardisation (click)
2. Regulation (EU) 2019/515 on mutual recognition of goods (click)
3. Directive 2001/95/EC of general safety of products (click)
4. Regulation (EC) 765/2008 on accreditation and CE marking (click)
5. Regulation (EU) 2019/1020 on market surveillance and compliance of products (click)
6. Directive (EU) 2019/2161 on consumer protection (click)
7. Directive (EU) 2019/771 on the sales of goods (click)
8. Directive 2000/31/EC on e-commerce (click)
9. Regulation (EC) 1935/2004 on food contact materials (click)
10. Directive 98/2008/EC on waste (Waste Framework Directive) (click)
11. Directive 98/83/EC on drinking water (click)

List of the key (most important in relation to household appliances) legislations from the Annex I. of Regulation (EU) 2019/1020 (harmonised product legislations):

1. Directive 94/62/EC on packaging and packaging waste
2. Directive 2000/14/EC on noise emission to the environment by equipment for use outdoors
3. Regulation (EC) No 648/2004 on detergens
4. Directive 2006/42/EC on machinery
5. Directive 2006/66/EC on batteries and accumulators (*Note: under amendment to regulation!*)
6. Regulation (EC) No 1907/2006 on REACH
7. Directive 2009/48/EC on the safety of toys
8. Directive 2009/125/EC on ecodesign
9. Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
10. Directive 2011/65/EU on RoHS
11. Directive 2012/19/EU on WEEE
12. Directive 2014/30/EU on electromagnetic compatibility (EMC)
13. Directive 2014/35/EU on low-voltage electrical equipment
14. Regulation (EU) No 517/2014 on F-gases
15. Regulation (EU) 2017/745 on medical devices
16. Regulation (EU) 2017/1369 on energy label