# ARISE PLUS Philippines

**BUSINESS GUIDE: EXPORTING TO THE EU MARKET** 

**ELECTRICAL PRODUCTS & ELECTRONICS** 









# ABOUT THE BUSINESS GUIDE

This Business Guide on Exporting Electrical Products and Electronics to the EU is part of a series of business guides developed for the Philippines.

These guides are developed under the ASEAN Regional Integration Support – Philippines Trade-Related Assistance Project for the Philippines (ARISE Plus Philippines), funded by the European Union. The International Trade Centre (ITC) is the technical agency implementing the ARISE Plus Philippines project. The Department of Trade and Industry (DTI) of the Philippines is the focal agency for the project.

Under the scope of the ARISE Plus Philippines project, ITC is providing support to strengthen the Philippines' access to the EU market, including by strengthening utilisation of the EU's unilateral trade preferences under the EU's Generalised Scheme of Preferences Plus (GSP+) scheme.

In this context, activities are underway to build awareness on and capacity to access the EU market and benefit from the opportunities delivered by the EU's unilateral trade preferences – including through the development of this series of business guides on exporting to the EU market, and making use of the GSP scheme, where relevant.

This Business Guide focuses on the electrical products and electronics sectors – providing information on access to the EU market, technical and regulatory requirements to be complied with in the Philippines to export electrical products and electronics to the EU and measures to meet to cross the EU border. This guide should be ready in conjunction with the general Business Guide.

Alongside the general Business Guide, the other sector-specific guides in the series cover the following sectors: agricultural products, processed food products, garments and textiles, and machinery. These sectors were prioritised drawing from their current export status, priorities in the Philippines' development plans, and GSP market access related concerns.

Information for the guide was collected over the period from March to October 2022.

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# **ABBREVIATIONS**

AC	Alternating current
ATEX	ATmosphere Explosible
DEHP	Bis(2-ethylhexyl) phthalate
BBP	Butyl benzyl phthalate
CN	Combined Nomenclature
DBP	Dibutyl phthalate
DIBP	Diisobutyl phthalate
DC	Direct current
DTI	Philippine Department of Trade and Industry
EIAPI	Electronics Industries Association of the Philippines, Inc.
ECCP	European Chamber of Commerce of the Philippines
CENELEC	European Committee for Electrotechnical Standardization
EU	European Union
EMB	Export Marketing Bureau
ESIA	The European Semiconductor Industry Association
EUR	Euro
FPI	Federation of Philippine Industries
FTSC	Foreign Trade Service Corps
GDP	Gross Domestic Product
GPSD	General Product Safety Directive
GSP	Generalised Scheme of Preferences Plus
GSP+	Generalised Scheme of Preferences Plus
HS	Harmonized System
i3S	Inclusive Innovation Industrial Strategy
IEC	International Electrotechnical Commission
ITC	International Trade Centre
LDCs	Least Developed Countries
LEDs	Light-emitting diodes
MFN	Most Favoured Nation
NSW	National Single Window
NSGL	National Strategic Goods List
OMB	Optical Media Board
PBB	Polybrominated biphenyls
PBDE	Polybrominated diphenyl ethers
PCCI	Philippine Chamber of Commerce and Industry
PESA	Federation Of Electrical and Electronics Suppliers and Manufacturers of
PHILEXPORT	the Philippines, Inc. Philippine Exporters Confederation, Inc.
RED	Radio Equipment Directive
REX	Registered Exporter

SEIPI	Semiconductor And Electronics Industries in the Philippines, Inc.		
STMA	Strategic Trade Management Act		
STMO	Strategic Trade Management Office		
USD	US Dollar		
WEEE	Waste electrical and electronic equipment		
WomenBizPH	Women's Business Council Philippines, Inc.		

# INTRODUCTION

The International Trade Center (ITC), Under the scope of the ARISE Plus Philippines project, is providing support to strengthen the Philippines' access to the EU market, including by making use of preferential market access benefits.

In this context, ITC is undertaking activities to build awareness on and capacity to access the EU market and benefit from the preferential market access opportunities available, including through the development of this series of business guides on exporting to the EU market and making use of the EU's GSP scheme, where relevant.

ITC has developed a General Business Guide for businesses seeking to export to the EU to understand market access opportunities available to the Philippines under the GSP+ scheme and requirements to comply with to export to the EU (at the domestic and EU level). The General Business Guide is the key general reference for exporting to the EU.

To complement the General Business Guide, a series of sector-specific business guides have been developed for target sectors in the Philippines exporting to the EU, providing detailed sector-specific information and discussing the respective market requirements.

## This Business Guide focuses on exports of electronics from the Philippines to the EU.

Materials reviewed include studies/information published by the EU and Philippine authorities, as well as the ITC Export Potential Analysis.

Key Steps	Summary of the main steps to be followed by Philippines exporters to the EU for the relevant products	
Context	Setting out the Philippines' current exports and potential for the relevant products, and other general information in this regard	
Technical Requirements	<ul> <li>Covering the <ul> <li>relevant tariffs/duties applicable,</li> <li>specifics of rules of origin requirements for products within the sector, and</li> <li>other technical export/import rules in relation to permits/licences, documentation, and checks at the borders</li> </ul> </li> </ul>	
Key Regulatory Requirements	Providing details on matters relating to relevant standards, technical regulations, and conformity assessment.	
Labelling Requirements	Setting out requirements for labelling of products	
Further Information and Key Contacts	Providing contact details for key agencies and business organizations in the EU and the Philippines, which can be contacted for the relevant sectors	

The Guide is organised as follows:

# MAIN STEPS FOR EXPORTING ELECTRICAL PRODUCTS

# Comply with the steps required in the Philippines

- \*
- Register the enterprise in accordance with local rules Prepare export documents
- Request and obtain an export clearances/permits (for regulated products)
- Fill out the relevant forms for customs clearance

# Comply with the importing requirements of the EU



- Check and ensure compliance with the applicable rules of origin
- Ensure registration with the EU's Registered Exporter (REX) system
- Request and obtain a product certification and declaration of conformity

# Comply with any product-specific rules that apply to products to be placed on the EU market:



- Check applicable import regimes for specific electrical and electronic equipment
- Check the EU rules for restricted hazardous substances
- Check the EU rules for low voltage electrical equipment
- Check the relevant EU standards on electrical and electronic equipment
- Check special rules, for instance for electronic toys
- Check for the Ecodesign and energy requirements

# **PART I**:

# The Philippines' Electrical Equipment and Electronics Exports to the EU market

**Electronics constitutes one of the Philippines' largest export sectors to the EU:** The sectors of electronic equipment and machinery account for the Philippines' largest export sectors not only to the world but also to the EU, accounting for almost 70% of total exports to the EU in 2021 when combined.<sup>1</sup>

Electronics has also been identified among the priority industry clusters under the Philippines' 'Science, Technology, and Innovation-based Industrial Strategy'. This sector has been noted as having high potential for growth as it aims at moving towards the manufacturing of higher value-added products to meet worldwide demand.<sup>2</sup>

The electronics sector has dominated Philippine exports in the past decade and is the largest contributor to its manufacturing sector.<sup>3</sup> In 2021, electronic products remained as the country's top export commodity with an export value of EUR 38.66 billion (USD 42.49), accounting for 56.9% of total exports (see Figure 1).<sup>4</sup>

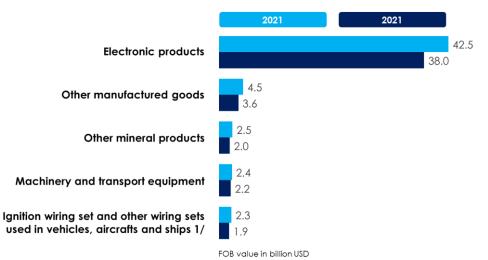


Figure 1: Philippine exports of Top Five Major Commodity Groups, 2020 and 2021<sup>5</sup>

Electronics are covered under Chapter 85 of *Commission Delegated Regulation (EU)* 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code.

Chapter 85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles		
	Description of goods		
ex 8501	Crystalline silicon photovoltaic modules or panels		
8527	Reception apparatus for radio-broadcasting, whether or not combined, in the same housing, with sound recording or reproducing apparatus or a clock		
8528	Monitors and projectors, not incorporating television reception apparatus; reception apparatus for television, whether or not incorporating radio-broadcast receivers or sound or video recording or reproducing apparatus		
8535	Electrical apparatus for switching or protecting electrical circuits, or for making connections to or in electrical circuits (for example, switches, fuses, lightning arresters, voltage limiters, surge suppressors, plugs and other connectors, junction boxes), for a voltage exceeding 1 000 volts		
ex 8536	Electrical apparatus for switching or protecting electrical circuits, or for making connections to or in electrical circuits (for example, switches, relays, fuses, surge suppressors, plugs, sockets, lamp-holders and other connectors, junction boxes), for a voltage not exceeding 1 000 volts		
ex 8537 10	Intelligent semiconductor-based motor-driver-module for control of electrical motordrives with variable speed settings for voltage < 1 000 V		
8541	Diodes, transistors and similar semiconductor devices; photosensitive semiconductor devices, including photovoltaic cells whether or not assembled in modules or made up into panels; light emitting diodes; mounted piezo-electric crystals		
ex 8541 (a)	Crystalline silicon photovoltaic cells, modules or panels		
ex 8541 (b)	other		
8542	Electronic integrated circuits		

Table 2 below provides an overview of the five largest markets exporting products under Chapters 85 to the EU, as well as the Philippines' exports in this sector.

Table 2: Key countries of	origin of exports and t	he Philippines export	s to the EU in 2021 <sup>6</sup>
······································			

HS Chapter	Sector	Country	Import value to the EU (EUR)
Chapter 85	Electrical machinery and equipment	1) China	142,877,404,115
	and parts thereof; sound recorders	2) Viet Nam	16,554,086,271
	and reproducers, television image	3) United States	15,393,827,336
	and sound recorders and	4) Taiwan	14,019,175,499
	reproducers, and parts and	5) Malaysia	13,783,081,307
	accessories of such articles	12) The Philippines	4,072,919,821

Key EU markets for exports of electrical machinery and equipment from the Philippines include Germany, the Netherlands, and France.

HS Chapter	Sector	The Philippines' overall exports to all destinations (in USD)	Exports to El States (in EU	
Chapter 85	Electrical machinery and equipment and parts thereof; sound recorders	38,074,314,000	Germany Netherlands	1,752,475 907,446
	and reproducers, television image		France	242,308
	and sound recorders and reproducers, and parts and accessories of such articles		Belgium	162,276

## Table 3: the Philippines exports to the world and to certain EU Member States in 2021<sup>7</sup>

Overall, the ITC *Export Potential Analysis* notes that the machinery and electronic equipment sectors have a combined export potential with a value of around EUR 72 billion, corresponding to almost three quarters of the total export potential. More specifically, the electronic equipment sector accounts for an export potential of USD 60 billion, while machinery and electricity account for EUR 10.9 billion.<sup>8</sup> According to the ITC's *Export Potential Analysis*, 45% of this export potential is still untapped. An ITC analysis indicates that export potential still appears to exist for a number of technologically advanced products.<sup>9</sup>

The ITC Export Potential Analysis further notes that the machinery and electricity subsector plays an important role in Philippine exports and that, more specifically, export potential exists in 161 different products in the subsector, and 114 of them are technologically advanced.<sup>10</sup> Based on the ITC *Export Potential Analysis*, these products still have a sizeable unrealised export potential in the EU. While East Asia is the most important market for Philippine exports of machinery and electronic equipment, with a total export potential to the region exceeding EUR 1.36 billion, the EU also operates as an important market in this sector with an export potential amounting to EUR 342 million.<sup>11</sup> In 2021, products such as machinery and electronic equipment, including hightech products (*i.e.*, aerospace, computers and office machines, electronics-telecommunications, pharmacy, scientific instruments, electrical machinery, chemistry, non-electrical machinery and armament) represented 19% of total EU imports.<sup>12</sup>

## Table 4: Export potential for the machinery and electronic equipment sectors<sup>13</sup>

Product	Unrealized export potential (values in USD '000)
Machinery and electronic equipment	3,570,359

These products are also the most important product sections for the Philippines under the EU GSP+ (see Figure 2). However, despite being the top Philippine exports to the EU, GSP utilization rates for these products remain at 70% (see Table 5).



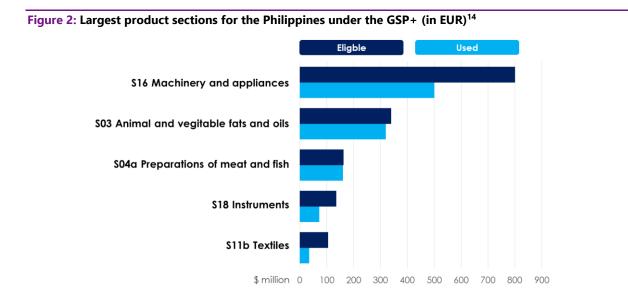


Table 5: EU import values and GSP utilisation for the machinery and electronic equipment sectors<sup>15</sup>

Product	EU Imports from PH 2021 (values in EUR)	GSP Utilisation
Chapter 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles	3,948,259,823	70.09%

A comparatively low GSP+ utilisation rate, in comparison to other GSP beneficiary countries, for products under HS Chapter 85 may be attributed to the already low MFN tariff rates for products in these chapters, as noted by the ITC *Export Potential Analysis*.



# Table 6: MFN tariffs and GSP+ rates for the machinery and electronic equipment sectors<sup>16</sup>

Product	MFN Tariff Rate/Range	GSP+ Rate
Non-electric machinery	0% - 9.7%	0%
Electric machinery	0% - 14%	0%

## This sector-specific guide for electronics has been developed as:



There are still electronic products subject to significant MFN tariff rates (as seen in Table 6 above) for which the GSP+ scheme would be relevant and can **provide Philippines' businesses with a competitive edge**;



In the EU, the electronics sector is highly regulated and therefore, exporters from the Philippines must take significant steps to ensure that relevant technical and regulatory requirements are met, particularly that environmental and safety requirements are taken into account; and



Given that there is also a significant export potential for such products in the EU market which has yet to be tapped into, it would be relevant for exporters to understand the export processes in place and requirements to comply to export to the EU.

# **PART II:** Utilising the EU GSP+ benefits for electrical equipment and electronic products from the Philippines

This section will focus on the relevant requirements for exports of electronic products from the Philippines to the EU to benefit from the preferential market access under the EU's GSP+ scheme.

# 2.1. Step 1: Tariff Preferences for exports of electronic equipment under the EU GSP+ scheme

The first step that a Philippine business must take is to determine the proper EU Combined Nomenclature (hereinafter, CN) code for the particular product it produces and intends to export.

Generally, for electronic products, the relevant chapter in the CN is Chapter 85.

As stated in Article 12(1) of the GSP Regulation, "*The Common Customs Tariff ad valorem duties on all products listed in Annex IX which originate in a GSP+ beneficiary country shall be suspended*". In Annex IX, Chapters 84 and 85 are included with no exceptions:

S-16	84	Chapter 84	Nuclear reactors, boilers, machinery and mechanical applications; parts thereof
	85	Chapter 85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers and parts and accessories of such articles

Accordingly, if the products intended for export fall under Chapter 85, then the products enter the EU duty-free and quota-free under the EU GSP+ scheme.<sup>17</sup>

# 2.2. Step 2: Ensure compliance with Rules of Origin requirements for electronic products

To claim tariff free entry to the EU market under the GSP+ scheme, the products *must originate from a beneficiary country.*<sup>18</sup>

The product is deemed to '*originate*' from the beneficiary country, when it has been:

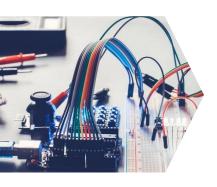
- "wholly obtained" in that country or
- "sufficiently worked or processed" in that country.

The rules of origin requirements for electronics are laid out in Part II of Annex 22-03 of <u>Commission Delegated</u> <u>Regulation (EU) 2015/2446</u><sup>19</sup> as demonstrated in Figure 3 below.

# Figure 3: Extract from table in Annex 22-03 on rules of origin for electrical and electronic equipment

### LIST OF PRODUCTS AND WORKING OR PROCESSING OPERATIONS WHICH CONFER ORIGINATING STATUS

Harmonised System heading	Description of product	Qualifying operation (Working or processing, carried out on non-orig- inating materials, which confers originating status)	
ex Chapter 85	Electrical machinery and equipment and parts thereof; sound recorders and repro- ducers, television image and sound recorders and repro- ducers, and parts and acces- sories of such articles; except for:	Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 70 % of the ex-works price of the product	
8501, 8502	Electric motors and generators; Electric generating sets and rotary converters	<ul> <li>(a) LDCs</li> <li>Manufacture from materials of any heading, except that of the product and of heading 8503</li> <li>or</li> <li>Manufacture in which the value of all the materials used does not exceed 70 % of the ex-works price of the product</li> </ul>	(b) Other beneficiary countries Manufacture from materials of any heading, except that of the product and of heading 8503 or Manufacture in which the value of all the materials used does not exceed 50 % of the ex- works price of the product
8513	Portable electric lamps designed to function by their own source of energy (for example, dry batteries, accumulators, magnetos), other than lighting equipment of heading 8512	<ul> <li>(a) LDCs</li> <li>Manufacture from materials of any heading, except that of the product</li> <li>or</li> <li>Manufacture in which the value of all the materials used does not exceed 70 % of the ex-works price of the product</li> </ul>	(b) Other beneficiary countries Manufacture from materials of any heading, except that of the product. or Manufacture in which the value of all the materials used does not exceed 50 % of the ex- works price of the product



In simple terms, for exporters from the Philippines, column 3 provides the minimum '*qualifying operation*' necessary for a material not originating from the Philippines to be deemed to have originated from the Philippines for the purposes of the EU's GSP+ scheme.

Accordingly, producers in the Philippines will need to review the chapters covering electronics in Annex 22-03 and identify the type of working and processing that should be undertaken in order for the final product to be deemed as originating from the Philippines.

Table 7 below summarises these requirements for Chapters 85 covering '*Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles*<sup>20</sup>

Chapter No.	Description of Product	Qualifying operation (working or processing, carried out on non-originating materials, which confers originating status)
Ex Chapter 85	Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles; except for:	Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 70% of the ex-works price of the product
8501, 8502	Electric motors and generators; Electric generating sets and rotary converters	<ul> <li>(a) (concerns LDCs)</li> <li>(b) Other beneficiary countries</li> <li>Manufacture from materials of any heading, except that of the product and of heading 8503 or</li> <li>Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product</li> </ul>
8513	Portable electric lamps designed to function by their own source of energy (for example, dry batteries, accumulators, magnetos), other than lighting equipment of heading 8512	<ul> <li>(a) (concerns LDCs)</li> <li>(b) Other beneficiary countries</li> <li>Manufacture from materials of any heading, except that of the product. or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product</li> </ul>
8519	Sound recording and sound reproducing apparatus	<ul> <li>(a) (concerns LDCs)</li> <li>(b) Other beneficiary countries</li> <li>Manufacture from materials of any heading, except that of the product and of heading 8522 or</li> <li>Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product</li> </ul>

# Table 7: Rules of origin for electrical and electronic equipment as set out in Annex 22-03

Chapter No.	Description of Product	Qualifying operation (working or processing, carried out on non-originating materials, which
		confers originating status)
8521	Video recording or reproducing	(a) (concerns LDCs)
	apparatus, whether or not incorporating a video tuner	(b) Other beneficiary countries
		Manufacture from materials of any heading, except that of the product and of heading 8522 or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8523	Discs, tapes, solid-state non-volatile	(a) (concerns LDCs)
	storage devices, 'smart cards' and other media for the recording of	(b) Other beneficiary countries
	sound or of other phenomena, whether or not recorded, including matrices and masters for the production of discs, but excluding products of Chapter 37	Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8525	Transmission apparatus for radio	(a) (concerns LDCs)
	broadcasting or television, whether or not incorporating reception	(b) Other beneficiary countries
	apparatus or sound recording or reproducing apparatus; television cameras, digital cameras and other video camera recorders	Manufacture from materials of any heading, except that of the product and of heading 8529 or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8526	Radar apparatus, radio navigational	(a) (concerns LDCs)
	aid apparatus and radio remote control apparatus	(b) Other beneficiary countries
		Manufacture from materials of any heading, except that of the product and of heading 8529 or
		Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8527	Reception apparatus for	(a) (concerns LDCs)
	radiobroadcasting, whether or not combined, in the same housing,	(b) Other beneficiary countries
	with sound recording or reproducing apparatus or a clock	Manufacture from materials of any heading, except that of the product and of heading 8529 or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8528	Monitors and projectors, not	(a) (concerns LDCs)
	incorporating television reception apparatus; reception apparatus for	(b) Other beneficiary countries
	television, whether or not	Manufacture from materials of any heading, except
	incorporating radio-broadcast receivers or sound or video recording or reproducing apparatus	that of the product and of heading 8529 or Manufacture in which the value of all the materials

Chapter No.	Description of Product	Qualifying operation (working or processing,
		carried out on non-originating materials, which confers originating status)
8528 (cont.)		used does not exceed 50% of the ex-works price of the product
8535 to 8537	Electrical apparatus for switching or	(a) (concerns LDCs)
	protecting electrical circuits, or for making connections to or in	(b) Other beneficiary countries
	electrical circuits; connectors for optical fibres, optical fibre bundles or cables; boards, panels, consoles, desks, cabinets and other bases, for electric control or the distribution of electricity	Manufacture from materials of any heading, except that of the product and of heading 8538 or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8540 11 and	Cathode ray television picture	(a) (concerns LDCs)
8540 12	tubes, including video monitor cathode ray tubes	(b) Other beneficiary countries
		Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
ex 8542 31,	Monolithic integrated circuits	Manufacture in which the value of all the materials
ex 8542 32,		used does not exceed 50% of the ex-works price of the product or The operation of diffusion, in which
ex 8542 33,		integrated circuits are formed on a semi-conductor
ex 8542 39	substrate by the selective introduction appropriate dopant, whether or not a and/or tested in a non-party	
8544	Insulated (including enamelled or	(a) (concerns LDCs)
	anodised) wire, cable (including coaxial cable) and other insulated	(b) Other beneficiary countries
	electric conductors, whether or not fitted with connectors; optical fibre cables, made up of individually sheathed fibres, whether or not assembled with electric conductors or fitted with connectors	Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8545	Carbon electrodes, carbon brushes, lamp carbons, battery carbons and other articles of graphite or other carbon, with or without metal, of a kind used for electrical purposes	Manufacture in which the value of all the materials used does not exceed 70% of the ex-works price of the product
8546	Electrical insulators of any material	(a) (concerns LDCs)
		(b) Other beneficiary countries
		Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8547	Insulating fittings for electrical	(a) (concerns LDCs)
	machines, appliances or equipment, being fittings wholly of insulating materials apart from any minor	(b) Other beneficiary countries

Chapter No.	Description of Product	Qualifying operation (working or processing, carried out on non-originating materials, which confers originating status)
		Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product
8548	Electrical parts of machinery or apparatus, not specified or included elsewhere in this Chapter	<ul> <li>(a) (concerns LDCs)</li> <li>(b) Other beneficiary countries</li> <li>Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product</li> </ul>
8549	Electrical and electronic waste and scrap	<ul> <li>(a) (concerns LDCs)</li> <li>(b) Other beneficiary countries</li> <li>Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 50% of the ex-works price of the product.</li> </ul>

# **Key Points to Note:**

- Exporters are encouraged to use the instructions/explanations provided in this guide to identify and understand the applicable rules of origin for electronics in Part II of Annex 22-03 of *Commission Delegated Regulation (EU) 2015/2446.*
- Philippine producers should note the exceptions to the rules of origin cumulation and derogation as explained further below.



# 2.2.1 Exception to RoO: Cumulation

Cumulation refers to a system that allows the origin of materials or processing undertaken in country A to be added to the materials and processing undertaken within country B, so long as they are further processed or added to products originating in country B. Cumulation can take place in the following ways:

	Principle	Applicability to the Philippines			
The two main types	The two main types of cumulation are:				
i. Bilateral Cumulation	Bilateral cumulation allows materials         originating in the EU to be counted as if         they were originating in the GSP         beneficiary country when used in         manufacturing a product.         Provided that certain requirements are         met:         materials <u>originating in the EU</u> (within the meaning of the EU's GSP rules of origin), and         further worked or processed in a beneficiary country.         are considered to originate in the beneficiary country. <sup>21</sup>	If a Philippine business imports material originating from the EU and these materials are further worked or processed in the Philippines, the product is considered as originating from the Philippines and, if the product is covered by the preferences, will be entitled to the GSP+ tariff preferences.			
ii. Regional Cumulation	Regional cumulation refers to a system         whereby products originating in a         country that is a member of a regional         group will be considered as materials         originating from another country of the         same regional group (or a country of         another regional group where         cumulation between groups is possible),         when further processed or incorporated         in a product manufactured there. <sup>22</sup> The EU's GSP recognises four regional         groups. <sup>23</sup> Accordingly,           Materials originating in one country         of the group,           which are further worked or         processed in another beneficiary         country of the same group,         are considered to originate in the latter         country. <sup>24</sup>	The Philippines is part of 'Group 1' from the four regional groups, along with Brunei, Cambodia, Indonesia, Malaysia, Myanmar, Thailand, and Viet Nam. <sup>25</sup> If a Philippine business imports material from any of the abovementioned countries that benefits from the GSP (namely Cambodia, Indonesia, and Myanmar) and this product is further worked or processed in the Philippines, the product can be considered as originating in the Philippines and, if the product is covered by the preferences, will be entitled to benefit from the GSP+ preferences.			
In addition, there a	In addition, there are also two other types of cumulation that could apply:				
iii. <b>Extended</b> Cumulation <sup>26</sup>	This is applied between the GSP beneficiary country and a country with which EU has a preferential trade agreement.	If a Philippine business imports materials from a country with which the EU has concluded a preferential trade agreement, such as Viet Nam, <sup>28</sup> and further works or processes these materials in the Philippines,			

# **Table 8: Types of cumulation**

	Principle	Applicability to the Philippines
Extended Cumulation (cont.)	Extended cumulation does not apply to products classified under Chapters 1 to 24 of the EU's Combined Nomenclature, which concerns agricultural and food products. <sup>27</sup>	the product can be taken as originating in the Philippines and, if the product is covered by the preferences, can be entitled to benefit from GSP+ preferences. (Provided that the products do not fall within the Chapters 1 – 24 of the CN).
iv. Cross- Regional Cumulation <sup>29</sup>	Cross-regional cumulation allows for GSP beneficiary countries from neighbouring regions ( <i>i.e.</i> , groups) to apply cumulation as though they were in the same region. For cross-regional cumulation to apply, the working and processing carried out must go beyond minimal operations. <sup>30</sup>	If a Philippine business imports materials from a GSP beneficiary from regional Group III ( <i>e.g.</i> , Bangladesh or Sri Lanka) and further works or processes these materials in the Philippines, the product can be taken as originating in the Philippines and if the product is covered by the preferences, can be entitled to benefit from GSP+ preferences. This type of cumulation is not granted automatically but is subject to a request. Currently there is only one such cumulation in place. <sup>31</sup>

# 2.2.2 Exception to RoO: Derogation from specific rules of origin

Derogations from the rules of origin may also be granted to beneficiary countries upon the European Commission's initiative or in response to a request from the beneficiary country.

This is only possible in case:

- internal or external factors temporarily deprive the country of the ability to comply with the applicable rules of origin where it could do so previously, or
- The country requires time to prepare itself to comply with the '*normal*' rules of origin.<sup>32</sup>

A specific request has to be made by the Government of the Philippines to the European Commission to obtain a derogation.



# **PART III:** Other Regulatory Requirements to Export Electrical Equipment and Electronics Products to the EU

Electronics imported or locally produced in the EU are subject to safety standards, labelling, documentation, and testing requirements. Philippine traders should, therefore, be aware of the various EU rules governing electronics.

# 3.1. CE Marking

CE marking is required for products such as electronics, medical devices, and machinery. The CE mark indicates that a product is compliant with the applicable EU directives and regulations. To obtain the CE mark, the product must undergo testing, as elaborated in Directive 2006/42/EC.

After undergoing the testing procedures, the test report (*i.e.,* a document that allows the certification body to issue the CE certificate) will be issued. After obtaining the test reports and the CE certificate, the manufacturer can issue the Declaration of Conformity and affix the CE mark to the machinery product.

The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the size or nature of that product, it is to be affixed to the packaging and to the accompanying documents. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm, though the minimum dimension may be waived for small-scale machinery.<sup>33</sup>

 Reposit' -usb	

### **Process for obtaining the CE Marking**

As the CE marking for machinery products is mandatory, Philippine exporters should check its compliance with the applicable safety and quality requirements. Philippine machine exporters could obtain a CE Marking from a notified body. A notified body is "*an organisation designated by an EU country to assess the conformity of certain products before being placed on the market*".<sup>34</sup>

Pursuant to Article 14 of Directive 2006/42/EC, EU Member States have to notify the European Commission and other EU Member States of the notified bodies that they have appointed to "*carry out* the assessment of conformity for placing on the market".

The list of appointed notified bodies is published by the Commission in the Official Journal of the European Union, and the Commission must keep the list up to date.<sup>35</sup> Currently, the list does not include notified bodies from the Philippines. However, there are some companies in the Philippines that offer assistance for exporters to obtain the CE marking:

Company Name	Link
Factocert	https://factocert.com/philippines/ce-mark-certification-in-philippines/
Société Générale de Surveillance (SGS)	https://www.sgs.com/en-ph/certified-clients-and-products#DD4
The British Standards Institution	https://www.bsigroup.com/en-PH/our-services/product-testing-and- certification/ce-marking/ce-markingfrequently-asked-questions/

# 3.2. Marketing requirements for electrical and electronic equipment: Safety Standards

EU rules relating to the marketing of electrical and electronic equipment concern mostly safety standards intended to ensure that electrical and electronic equipment imported into the EU are safe for humans, animals, and the environment. Key EU legislation and guidelines on mandatory safety requirements for electrical and electronic equipment are:

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment,<sup>36</sup>
- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility,<sup>37</sup>
- Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits,<sup>38</sup>
- Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011;<sup>39</sup>
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE),<sup>40</sup> and
- Commission Notice Guidelines for economic operators and market surveillance authorities on the practical implementation of Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products (2021/C 100/01).<sup>41</sup>

Notably, four out of the five EU legal instruments listed above and providing safety requirements for electrical and electronic equipment are Directives. EU Directives set the general rules and requirements and must be implemented in national law by all EU Member States. Exporters of electrical and electronic equipment from the Philippines must consider that EU Member States could have variations in safety requirements for electrical and electronic equipment. Additionally, the placing on the EU market of equipment for use outdoors is subject to compliance with mandatory noise emission requirements established by *Directive 2000/14/EC.*<sup>42</sup> This means that electrical and electronic equipment for outdoor use would need to comply with the requirements established by *Directive 2000/14/EC.* 

# 3.2.1 Restriction of hazardous substances (RoHS) in electrical and electronic equipment

In order to ensure a high-level protection of human health, animals, and the environment, imports into the EU of electrical and electronic equipment must comply with EU legislation to prevent the production and disposal of hazardous waste and to promote reuse, recycling, and other forms of recovery of such waste electrical and electronic equipment. The <u>EU Directive on the Restriction on Hazardous</u> <u>Substances</u> regulates the use of hazardous substances in electrical and electronic equipment, by restricting the use of chemicals and heavy metals in electronic components, solders, and casing materials.<sup>43</sup> The EU Directive on the Restriction on Hazardous Substances also contains rules on the collection and recycling of electrical and electronic equipment.

#### **Product scope**

The EU Directive on the Restriction on Hazardous Substances applies to the following categories of electrical and electronic equipment:<sup>44</sup>

- Household appliances;
- IT and telecommunications equipment;
- Lighting products;
- Electrical and electronic tools;
- Electronic toys;
- Electronic sports equipment;
- Medical devices;
- Monitoring instruments;
- Automatic dispensers; and
- Other electrical and electronic equipment not covered by any of the categories above.

Traders from the Philippines must ensure that their electrical and electronic equipment does not contain hazardous substances in amounts exceeding the following maximum concentration values set out in Annex II to *Directive 2011/65/EU*.<sup>45</sup> The restricted substances and maximum concentration values tolerated by weight in homogeneous materials allowed in electrical and electronic equipment are provided in Annex II to *Directive 2011/65/EU*.

Exemptions to the use of the restricted substances are provided in Annex III and Annex IV to *Directive 2011/65/E*U.

Restricted substances and maximum concentration values tolerated by weight in homogeneous materials

Lead (0,1 %) Mercury (0,1 %) Cadmium (0,01 %) Hexavalent chromium (0,1 %) Polybrominated biphenyls (PBB) (0,1 %) Polybrominated diphenyl ethers (PBDE) (0,1 %) Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %) Butyl benzyl phthalate (DBP) (0,1 %) Dibutyl phthalate (DIBP) (0,1 %)

Since 22 July 2021, the restrictions regarding Bis(2ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP) apply to medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments.<sup>46</sup>

### Obligations of the manufacturer, importers, and distributors<sup>47</sup>

Article 7 of *Directive 2011/65/EU* sets out the obligations for manufacturers of electrical and electronic equipment. Before exporting electrical and electronic equipment to the EU, manufacturers in the Philippines must ensure that:

- Their products comply with the EU's requirements on hazardous substances (Article 4 of *Directive* 2011/65/EU);
- They draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to *Decision No 768/2008/EC* or have it carried out and maintain the required technical documentation relating to the EU declaration of conformity;<sup>48</sup> and
- Affix the CE marking to the finished product or to its data plate. Exporters from the Philippines must ensure that manufacturers have met their obligations and that only compliant products are placed on the EU market.

Article 9 of *Directive 2011/65/EU* then sets out the obligations for importers of electrical and electronic equipment into the EU. Philippine exporters of electrical and electronic equipment should be aware that EU Member States must ensure that:

- " (a) importers place only EEE that complies with this Directive on the Union market;
- (b) importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking<sup>49</sup> and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points (g) and (h) of Article 7,<sup>50</sup>
- (c) where an importer considers or has reason to believe that an EEE is not in conformity with Article
   4, that importer does not place the EEE on the market until it has been brought into conformity,

and that that importer informs the manufacturer and the market surveillance authorities to that effect;

- (d) importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;
- (e) importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- (f) importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken;
- (g) importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;
- (h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market" (emphasis added).

For traceability reasons, exporters should ensure that:

- 1) The manufacturer's name or registered trademark and contact address is indicated; and
- 2) The equipment is marked with respect to type, batch or serial number or other element allowing its identification.

#### **Market surveillance**

Products may be placed on the EU market only if there is an economic operator (*i.e.*, manufacturer, importer, or an authorised representative) located in the EU acting as a liaison point with the market surveillance authorities of EU Member States. The EU market surveillance rules are laid down in <u>Regulation (EU)</u> <u>2019/1020</u><sup>51</sup> Exporters from the Philippines to the EU will have to work with an economic operator in the EU, whose contact details must be clearly visible on the electrical and electronic equipment or the packaging. Details are provided in Article 4 of <u>Regulation (EU)</u> <u>2019/1020</u>.

## 3.2.2 Waste electrical and electronic equipment (WEEE)

The EU maintains rules to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste from electrical and electronic equipment (WEE). In this *Directive* 2012/19/EU<sup>52</sup> context, establishes responsibilities for producers or their authorised representatives, regarding the management of 'waste electrical and electronic equipment (WEEE). Article 3 of *Directive 2012/19/EU* defines 'waste electrical and electronic equipment' as "electrical or electronic equipment which is waste within the meaning of Article *3(1) of Directive 2008/98/EC<sup>53</sup>, including all* components, sub-assemblies and consumables which are part of the product at the time of discarding".54

Exporters of the following categories of electrical and electronic equipment listed in Annex III to *Directive* <u>2012/19/EU</u> must comply with EU rules on the management of '*waste electrical and electronic equipment*':

- 1) Temperature exchange equipment
- 2) Screens, monitors, and equipment containing screens having a surface greater than 100 cm<sup>2</sup>
- 3) Lamps
- 4) Large equipment (any external dimension more than 50 cm) including, but not limited to: Household appliances; IT and telecommunication equipment; consumer equipment; luminaires; equipment reproducing sound or images, musical equipment; electrical and electronic tools; toys, leisure and sports equipment; medical devices; monitoring and control instruments; automatic dispensers; equipment for the generation of electric

currents. This category does not include equipment included in categories 1 to 3.

- 5) Small equipment (no external dimension more than 50 cm) including, but not limited to: Household appliances; consumer equipment; luminaires; equipment reproducing sound or images, musical equipment; electrical and electronic tools; toys, leisure and sports equipment; medical devices; monitoring and control instruments; automatic dispensers; equipment for the generation of electric currents. This category does not include equipment included in categories 1 to 3 and 6.
- Small IT and telecommunication equipment (no external dimension more than 50 cm)

Exporters can find further information in Annex IV to *Directive 2012/19/EU* on electrical and electronic equipment that fall within the categories listed in Annex III to *Directive 2012/19/EU*.

In order to comply with *Directive 2012/19/EU*, exporters of electrical and electronic equipment from the Philippines to the EU should:

- Ensure that the design and production facilitate reuse, dismantling, and recovery of their products;<sup>55</sup>
- Ensure that the equipment is appropriately marked, preferably in accordance with the European standard EN 50419, with the symbol shown in Annex IX to *Directive 2012/19/EU*. The symbol is intended to facilitate the separate collection of electrical and electronic waste. The symbol must be placed printed

on the packaging, on the instructions for use and on the warranty (see Figure 4 below);<sup>56</sup>

- Ensure that there are established individual or collective systems for the collection, treatment and recovery of WEEE. Exporters can find details on the recovery targets in Annex V to *Directive* 2012/19/EU<sup>57</sup>
- Provide for a guarantee for the financing of the collection, treatment, recovery and sound disposal of waste arising from their products;<sup>58</sup>
- Provide information for users and treatment facilities on the re-use and treatment for new electrical and

electronic equipment within one year of placing it onto the market,  $^{\rm 59}$ 

Register with the competent authority appointed by the Member State to which the equipment is to be exported and comply with the data reporting requirements relating to the amount and categories of equipment put on the EU market and relevant levels of recycling achieved. Exporters can find further information on the information to submitted for registration and reporting requirements in Annex X to Directive 2012/19/EU.<sup>60</sup>

# Figure 4: Annex IX to Directive 2012/19/EU provides the symbol that must be printed on the packaging, instructions for use, and warranty of the equipment



The Annex notes that "The symbol indicating separate collection for EEE consists of the crossedout wheeled bin, as shown below. The symbol must be printed visibly, legibly and indelibly".

# 3.2.3 Technical standards for electromagnetic compatibility

The EU <u>Electromagnetic Compatibility (EMC) Directive</u> <u>2014/30/EU</u> lays down mandatory requirements for electrical and electronic apparatus placed on the EU market.<sup>61</sup>

The EU's Electromagnetic Compatibility (EMC) *Directive* <u>2014/30/EU</u> aims at ensuring that the performance of electrical and electronic equipment is protected against electromagnetic disturbances.

In general terms, an electromagnetic disturbance interrupts, obstructs, or otherwise degrades or limits the effective performance of electrical and electronic equipment. *Directive 2014/30/EU* covers products that can either generate electromagnetic disturbance or might have their performance affected by such disturbance.

The EU's electromagnetic compatibility rules apply to all equipment as defined in Article 3(1) of <u>Directive</u> <u>2014/30/EU</u> and means 'apparatus' and 'fixed installation'.

- "'apparatus' means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance";<sup>62</sup> and
- "'fixed installation' means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location".<sup>63</sup>

Information on equipment **not covered** by the EU's rules on electromagnetic disturbances is provided in Article 2(2) of *Directive 2014/30/EU*.

Exporters of electronic equipment from the Philippines to the EU should ensure that the equipment complies with the essential requirements in Annex I to <u>Directive</u> <u>2014/30/EU</u>.

1. Ge	eneral requirements	<ul> <li>Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:</li> <li>(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended; and</li> <li>(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.</li> </ul>
	pecific requirements r fixed installations	Installation and intended use of components A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in point 1.

## Harmonised standards

Harmonised standards are technical specifications that facilitate compliance with essential requirements. Importantly, equipment manufactured according to established harmonised standards benefit from a presumption of compliance with the essential requirements in Annex I to *Directive 2014/30/EU*.<sup>64</sup> Exporters of electrical and electronic equipment from the Philippines to the EU should be aware of the harmonised standards developed by the following European Standardisation bodies:

European Committee for Electrotechnical Standardization (CENELEC); <sup>65</sup> and

# **Conformity assessment**

Before placing equipment covered by *Directive* 2014/30/EU on the EU market, exporters from the Philippines to the EU should ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. The conformity assessment process is required to certify that products comply with the essential requirements set out in Annex I to *Directive 2014/30/EU*.<sup>68</sup>

European Telecommunications Standards Institute (ETSI).<sup>66</sup>

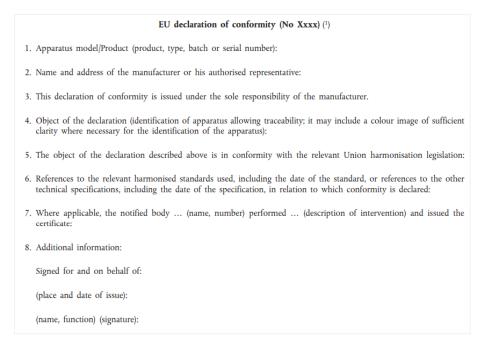
Harmonised standards developed by the European Standardisation bodies are voluntary. The standards are published in the Official Journal of the EU and transposed into national legislation in the form of national standards of the EU Member States. On its websites, the European Commission provides further information on harmonised standards on electromagnetic compatibility and the various amendments thereto.<sup>67</sup>

Exporters of equipment covered by *Directive* 2014/30/EU (*i.e.*, products or fixed installations "*liable* to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance"<sup>69</sup>) should take note of the conformity assessment options set out in Article 14 of Directive 2014/30/EU.<sup>70</sup>

Conformity assessment procedures for apparatus	Compliance of apparatus with the essential requirements set out in Annex I shall be demonstrated by means of either of the following conformity assessment procedures:
	(a) internal production control set out in Annex II; and
	(b) EU type examination that is followed by Conformity to type based on internal production control set out in Annex III.
	The manufacturer may choose to restrict the application of the procedure referred to in point (b) of the first paragraph to some aspects of the essential requirements, provided that for the other aspects of the essential requirements the procedure referred to in point (a) of the first paragraph is applied.

Exporters of covered equipment by Directive 2014/30/EU should take note of the conformity assessment procedures set out in Annex II and Annex III of that Directive. As part of the conformity assessment under *Directive 2014/30/EU*, manufacturers or the authorised representative must prepare an EU declaration of conformity in compliance with the model presented in Annex IV to *Directive 2014/30/EU*.<sup>71</sup>

## Figure 5: EU declaration of conformity



Exporters of equipment covered by *Directive* 2014/30/EU should take note of additional requirements regarding the EU declaration of conformity provided in Article 15 of *Directive* 2014/30/EU.

Manufacturers of equipment covered by *Directive* 2014/30/EU must compile the technical documentation, which enables to assess whether the products comply with the requirements of Annex II and Annex III to *Directive 2014/30/EU*.<sup>72</sup> The technical documentation,

together with a copy of the EU declaration of conformity, must be kept at the disposal of the competent national authorities designated by the EU Member States for inspection purposes for a period of 10 years after the equipment have been placed on the EU market.<sup>73</sup> Exporters of equipment covered by Directive 2014/30/EU from the Philippines to the EU, should take note of the additional obligations of economic operators (i.e., manufacturers, authorised representatives, importers, distributors) in Articles 7, 8, 9, 10 and 11 of Directive 2014/30/EU

## **CE marking**

Before being placed on the EU market, electrical and electronic equipment covered by *Directive 2014/30/EU* must bear the '*CE marking*' in order to attest that the equipment complies with the essential requirements of *Directive 2014/30/EU*.<sup>74</sup>

Exporters from the Philippines to the EU must ensure that the '*CE marking*' is affixed visibly, legibly and indelibly to the equipment or to its data plate. Where that is not possible or not warranted on account of the size or nature of that product, exporters must ensure that the '*CE marking*' is affixed to the packaging and to the accompanying documents.<sup>75</sup>

Exporters should take note of the general principles of *CE marking* set out in Article 30 of *Regulation (EC) No 765/2008* and the model of the CE marking in Annex II to *Regulation (EC) No 765/2008*.<sup>76</sup>

Figure 6: The European Conformity ("Conformite Europeenne", CE) marking Annex II of Regulation (EC) No 765/2008



#### **Further information**

For further information on Directive 2014/30/EU, the European Commission provides the following information:

Information on:	Link
List of Notified Bodies under	https://ec.europa.eu/growth/tools-
Directive 2014/30/UE	databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=153681
List of Central Contact Points in	https://ec.europa.eu/docsroom/documents/43062
charge of market surveillance	
under Directive 2014/30/UE	
Market surveillance for products	https://ec.europa.eu/growth/single-market/goods/building-blocks/market-
	surveillance en

### 3.2.4 Technical standards for low voltage electrical equipment

In order to ensure a high level of protection of the health and safety of persons, domestic animals or property, the EU established principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits set out in Annex 1 to *Directive 2014/35/EU.*<sup>77</sup>

#### **Product scope**

Directive 2014/35/EU covers electrical equipment (including some components intended for incorporation into other equipment) designed for the use with a voltage rating:<sup>78</sup>

The EU's safety objectives specified in *Directive* 2014/35/EU aim at providing protection against risks arising from the use of the electrical equipment and risks that may be caused by external influences on the electrical equipment, including not just electrical ones but also mechanical, chemical and any other risk such as noise, and vibrations.

- between 50 and 1000 V for alternating current;
- between 75 and 1500 V for direct current.

- In particular, products such as electrical appliances, lighting equipment, electric wiring, appliance couplers and cord sets, or electrical installation equipment, are covered by *Directive 2014/35/EU*.
- Exporters can find further detail on equipment outside the scope of the Directive listed in Annex II to *Directive 2014/35/EU*.

Equipment and phenomena outside the scope of Directive 2014/35/EU	Electrical equipment for use in an explosive atmosphere Electrical equipment for radiology and medical purposes Electrical parts for goods and passenger lifts Electricity meters Plugs and socket outlets for domestic use Electric fence controllers Radio-electrical interference Specialised electrical equipment, for use on ships, aircraft or railway which complies with the safety provisions drawn up by internation bodies in which the Member States participate Custom built evaluation kits destined for professionals to be used sole				
	Custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes				

# **Essential requirements**

Exporters of low-voltage electrical equipment from the Philippines to the EU must comply with the safety

objectives for electrical equipment established in Annex I to Directive 2014/35/EU.

# Principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits

1. General conditions	<ul> <li>(a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document;</li> <li>(b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected; and</li> <li>(c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured</li> </ul>
2. Protection against hazards arising from the electrical equipment	<ul> <li>Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:</li> <li>(a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact;</li> <li>(b) temperatures, arcs or radiation which would cause a danger, are not produced;</li> <li>(c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience; and</li> <li>(d) the insulation is suitable for foreseeable conditions.</li> </ul>
3. Protection against hazards which may be caused by external influences on the electrical equipment	<ul> <li>Technical measures shall be laid down in accordance with point 1, in order to ensure that the electrical equipment:</li> <li>(a) meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;</li> </ul>

(b)	is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered; and
(c)	does not endanger persons, domestic animals and property in foreseeable conditions of overload.

# Harmonised standards

Electrical equipment manufactured according to established harmonised standards benefits from a presumption of compliance with the essential safety requirements.<sup>79</sup>

Exporters of electrical equipment covered by *Directive 2014/35/EU* should take note of harmonised standards developed by the European Standardisation body, the European Committee for Electrotechnical Standardization (CENELEC).<sup>80</sup>

In the absence of European harmonised standards, exporters should take note of international rules issued by the International Electrotechnical Commission (IEC).<sup>81</sup> that apply to exports of electrical equipment covered by *Directive 2014/35/EU*.<sup>82</sup> In the absence of harmonised standards by the European Standardisation body and in the absence of international standards, exporters should comply with the national standards of the EU Member States to which the equipment would be exported.<sup>83</sup>

Figure 7: An extract of the summary of references of harmonised standards published in the EU's Official Journal relating to Directive 2014/35/EU<sup>84</sup>

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)	Restriction (3)	Date of start of presumption of conformity with restriction (4)	OJ reference for publication of a restriction in OJ (5)	Date of withdrawal from OJ (end of presumption of conformity) (6)	OJ reference for withdrawal from OJ (7)
2014/35/EU	CEN	EN 13637:2015	Building hardware - Electrically controlled exit systems for use on escape routes - Requirements and test methods	20/04/2016	OJ C 249 - 08/07/2016	-		-		-
2014/35/EU	Cenelec	HD 308 \$2:2001	Identification of cores in cables and flexible cords	20/04/2016	OJ C 249 - 08/07/2016	-		-		-
2014/35/EU	Cenelec	HD 361 S3:1999, HD 361 S3:1999/A1:2006, HD 361 S3:1999/AC:1999	System for cable designation	20/04/2016	OJ C 249 - 08/07/2016	-		-		-
2014/35/EU	Cenelec	HD 368 \$1:1978	Direct acting recording electrical measuring instruments and their accessories	20/04/2016	OJ C 249 - 08/07/2016	-		-		-
2014/35/EU	Cenelec	HD 516 82:1997, HD 516 82:1997/A1:2003, HD 516 82:1997/A2:2008	Guide to use of low voltage harmonized cables	20/04/2016	OJ C 249 - 08/07/2016	-		-	17/02/2017	OJ C 249 - 08/07/2016
2014/35/EU	Cenelec	HD 549 81:1989	Conference systems - Electrical and audio requirements	20/04/2016	OJ C 249 - 08/07/2016	-		-		-
2014/35/EU	Cenelec	HD 597 81:1992, HD 597 81:1992/AC:1992	Coupling capacitors and capacitor dividers	20/04/2016	OJ C 249 - 08/07/2016	-		-		-

Exporters of electrical equipment covered by *Directive 2014/35/EU* can find further information on the harmonised standards on the EU's website on harmonised standards in the context of *Directive 2014/35/EU*.<sup>85</sup>

### **Conformity assessment**

The conformity assessment process declares that equipment complies with the rules laid down in *Directive 2014/35/EU*. Before placing electrical equipment covered by *Directive 2014/35/EU* on the EU market, exporters from the Philippines to the EU should ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer.<sup>86</sup> The conformity assessment

procedures to be followed are established in Annex III module A to *Directive 2014/35/EU*.

As part of the conformity assessment, the manufacturer or the authorised representative must draw up an EU declaration of conformity in compliance with the model presented in Annex IV to *Directive 2014/35/EU*.

### Figure 8: Model of the EU declaration of conformity in Annex IV to Directive 2014/35/EU

#### EU DECLARATION OF CONFORMITY (No XXXX) (1)

- 1. Product model/product (product, type, batch or serial number):
- 2. Name and address of the manufacturer or his authorised representative:
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
- 4. Object of the declaration (identification of electrical equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the electrical equipment):
- 5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
- 6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
- 7. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

The manufacturer must compile the technical documentation, which enables to assess whether the products comply with the requirements of the *Directive 2014/35/EU*.<sup>87</sup> The technical documentation, together with a copy of the EU declaration of conformity, must be kept at the disposal of the competent national authorities for inspection purposes for a period of 10 years after the equipment have been placed on the market.<sup>88</sup>

Exporters of equipment covered by *Directive* 2014/35/EU from the Philippines to the EU should take note of the obligations of economic operators, which includes specific obligations for manufacturers,

authorised representatives, importers and distributors. Notably, manufacturers must ensure that electrical equipment has been designed and manufactured in accordance with the safety objectives specified in *Directive 2014/35/EU*.<sup>89</sup>

Before being placed on the EU market, as well as in the case of products or fixed installations "*liable to generate electromagnetic disturbance*", electrical equipment covered by *Directive 2014/35/EU* must bear the *CE marking* in order to attest that the equipment complies with applicable essential requirements.<sup>90</sup>

# **Further information**

For further information on *Directive 2014/35/EU*, the European Commission provides the following:

Information on:	Link				
Harmonised Standards - Low	https://ec.europa.eu/growth/single-market/european-standards/harmonised-				
voltage (LVD)	standards/low-voltage/				
Low Voltage Directive (LVD)	https://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive/				
Market surveillance for products	https://ec.europa.eu/growth/single-market/goods/building-blocks/market-				
	surveillance en				



# 3.3. Energy efficiency requirements

# 3.3.1 Ecodesign and energy labelling requirements

The <u>EU legislation on energy labelling and ecodesign</u> seeks to "*improve the energy efficiency of products on the EU market*". The European Commission notes that the "*Ecodesign sets common EU wide minimum*  standards to eliminate the least performing products from the market. The energy labels provide a clear and simple indication of the energy efficiency and other key features of products at the point of purchase".<sup>91</sup>

### **Elements covered**

The EU's Ecodesign legislation and energy labelling legislation lay down the requirements for ecodesign, energy consumption, technical documentation, and energy labelling for electronics placed on the EU

market. These regulations mainly cover home appliances, but also computers, power supplies, and LED lighting products. The EU's **Ecodesign rules** are set out in the following two legal instruments:

Legal instrument	Description
Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products <sup>92</sup>	Directive 2009/125/EC provides the framework for setting requirements that the energy-related products must fulfil in order to be placed on the EU market.
	Directive 2009/125/EC aims at contributing "to sustainable development by increasing energy efficiency and the level of protection of the environment, while at the same time increasing the security of the energy supply". <sup>93</sup>
<u>Commission Regulation (EU) 2016/2282 of 30</u> <u>November 2016 amending Regulations (EC) No</u> <u>1275/2008, (EC) No 107/2009, (EC) No 278/2009,</u> (EC) No 640/2009, (EC) No 641/2009, (EC) No <u>642/2009, (EC) No 643/2009, (EU) No 1015/2010,</u> (EU) No 1016/2010, (EU) No 327/2011, (EU) No	Commission Regulation (EU) 2016/2282 provides for verification tolerances that are designed to allow for variations that emerge in the measurements taken during verification tests carried out by EU Member States' surveillance authorities.
(EU) NO 1010/2010, (EU) NO 327/2011, (EU) NO 206/2012, (EU) No 547/2012, (EU) No 932/2012, (EU) No 617/2013, (EU) No 666/2013, (EU) No 813/2013, (EU) No 814/2013, (EU) No 66/2014, (EU) No 548/2014, (EU) No 1253/2014, (EU) 2015/1095, (EU) 2015/1185, (EU) 2015/1188, (EU) 2015/1189 and (EU) 2016/2281 with regard to the use of tolerances in verification procedures. <sup>94</sup>	Recital 2 of Commission Regulation (EU) 2016/2282 notes that variations in measures "are due to the differences in the measurement equipment used by manufacturers, importers and surveillance authorities across the Union". Manufacturer and exporters from the Philippines should note that verification tolerances should not be "used for establishing the values in the technical documentation or for interpreting those values in order to achieve compliance with ecodesign rules or to communicate better performance than has actually been measured and calculated. The parameters declared or published by the manufacturer or importer should not be more favourable for the manufacturer or importer than the values contained in the technical documentation". <sup>95</sup>

The EU's energy labelling requirements for electronic equipment are set out in <u>Regulation (EU)</u> 2017/1369 of the European Parliament and of the <u>Council of 4 July 2017 setting a framework for energy</u> labelling and repealing Directive 2010/30/EU.<sup>96</sup>

Additional general rules and guidance on electronic equipment can be found in the following Commission delegated regulations and Notice:

 Commission Delegated Regulation (EU) 2017/254

 of 30 November 2016 amending Delegated

 Regulations (EU) No 1059/2010, (EU) No

 1060/2010, (EU) No 1061/2010, (EU) No 1062/2010,

 (EU) No 626/2011, (EU) No 392/2012, (EU) No

 874/2012, (EU) No 665/2013, (EU) No 811/2013,

 (EU) No 812/2013, (EU) No 65/2014, (EU) No

 1254/2014, (EU) 2015/1094, (EU) 2015/1186 and

(EU) 2015/1187 with regard to the use of tolerances in verification procedures;<sup>97</sup>

Commission Delegated Regulation (EU) No 518/2014 of 5 March 2014 amending Commission Delegated Regulations (EU) No 1059/2010, (EU) No 1060/2010, (EU) No 1061/2010, (EU) No 1062/2010, (EU) No 626/2011, (EU) No 392/2012, (EU) No 874/2012, (EU) No 665/2013, (EU) No 811/2013 and (EU) No 812/2013 with regard to labelling of energy-related products on the internet;<sup>98</sup> and

Commission Notice on the application of energy labelling requirements for electronic displays, household washing machines and washer-dryers, refrigerating appliances and household dishwashers, and of ecodesign requirements on the provision of information for external power supplies.<sup>99</sup>

## **Product scope**

The European Commission provides for a list of **27 product groups** that fall within the scope of Ecodesign legislation and energy labelling legislation.<sup>100</sup> Additionally, the list provides for specific Regulations that apply to the various product groups. Exporters of

#### Product groups:

- 1) Air conditioners
- 2) Domestic ovens and range hoods
- 3) Electrical lamps and luminaires
- 4) Household dishwashers
- 5) Household refrigerating appliances
- 6) Household tumble driers
- 7) Household washing machines and washerdryers
- 8) Local space heaters
- 9) Professional refrigerated storage cabinets
- 10) Residential ventilation units
- 11) Solid fuel boilers and packages of a solid fuel boiler, supplementary heaters, temperature controls and solar devices
- 12) Space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device
- 13) Electronic displays and televisions
- 14) Vacuum cleaners
- 15) Water heaters, hot water storage tanks and packages of water heater and solar device

electronic equipment from the Philippines to the EU should carefully review the list to determine whether their products fall within the scope of the EU's Ecodesign legislation and energy labelling legislation, as well as the applicable product specific regulations.

- 16) Air heating products, cooling products, high temperature process chillers and fan coil units
- 17) Circulators (glandless standalone circulators and glandless circulators integrated in products)
- 18) Computers and computer servers
- 19) Electric motors
- 20) External power supplies (no-load condition electric power consumption and average active efficiency of external power supplies)
- 21) Fans driven by motors with an electric input power between 125 W and 500 kW
- 22) Simple set-top boxes
- 23) Small, medium and large power transformers
- 24) Standby and off mode electric power consumption of electrical and electronic household and office equipment
- 25) Water pumps
- 26) Welding equipment
- 27) Refrigerating appliances with a direct sales function

# List of energy efficient product regulations by product group:

The European Commission has published the following list of energy efficient product regulations by product group:<sup>101</sup>

Product groups	Energy labelling legislation	Ecodesign legislation
	<ul> <li>Framework Regulation:(EU) 2017/1369</li> <li>Use of tolerances: Regulation (EU) 2017/254</li> <li>Internet labelling: Regulation (EU) No 518/2014</li> <li>Covid-19 and application of 4 rescaled labels: 2020/C 182/02</li> </ul>	Framework Directive: <u>2009/125/EC</u> Use of tolerances: <u>Regulation (EU)</u> <u>2016/2282</u>
Air conditioners	(EU) No 626/2011 Harmonised standards: <u>2014/C</u> <u>110/01</u> and <u>2018/C 092/03</u>	(EU) No 206/2012 Impact Assessment [SWD(2012) 35] Impact Assessment Summary [SWD(2012) 34] Harmonised standards: 2012/C 172/01, 2014/C 110/01 and 2018/C 092/03
Domestic ovens and range hoods	(EU) No 65/2014 Harmonised standards: <u>2017/C</u> <u>267/01</u> Guidelines – May 2015	(EU) No 66/2014Impact Assessment [SWD(2014) 4]Impact Assessment Summary[SWD(2014) 3]Harmonised standards: 2017/C267/01Guidelines – May 2015
Electrical lamps and luminaires	(EU) No 874/2012 Harmonised standards: (2014/C 22/02) Guidelines – July 2015 NB: From 25 December 2019 onwards, the labelling of luminaires will no longer be required Repealed by (EU) 2019/2015 in application since 1 September 2021 Amended by (EU) 2021/340	<ul> <li>(EC) No 244/2009         <ul> <li>Transitional methods of measurement and calculation: 2014/C 22/02</li> <li>Guidelines – July 2015</li> </ul> </li> <li>Amended by (EC) No 859/2009         <ul> <li>Impact Assessment [SEC(2009) 327]</li> <li>Impact Assessment Summary [SEC(2009) 328]</li> <li>(EC) No 245/2009</li> <li>Transitional methods of measurement and calculation: 2014/C 22/02</li> <li>Guidelines – July 2015</li> </ul> </li> <li>Amended by (EU) No 347/2010         <ul> <li>Impact Assessment [SEC(2009) 324]</li> <li>Impact Assessment Summary [SEC(2009) 325]</li> <li>(EU) No 1194/2012</li> <li>Impact Assessment [SWD(2012) 419]</li> <li>Impact Assessment Summary [SWD(2012) 418]</li> </ul> </li> </ul>

Product groups	Energy labelling legislation	Ecodesign legislation
Electrical lamps and luminaires (cont.)		<ul> <li>Communication on the market assessment on the mains-voltage lamps <u>COM/2015/0443</u></li> <li>Transitional methods of measurement and calculation: <u>2014/C 22/02</u></li> <li><u>Guidelines – July 2015</u></li> <li>(EU) 2015/1428 (amending Regulations (EC/EU) 244/2009, 245/2009 and 1194/2012)</li> <li>Repealed by (EU) 2019/2020 – in application from 1 September 2021</li> <li>Impact Assessment [SWD/2019/0357]</li> <li>Executive Summary of the Impact Assessment [SWD/2019/0358]</li> </ul>
Household dishwashers	(EU) 2019/2017 Amended by (EU) 2021/340	(EU) 2019/2022Impact Assessment[SWD/2019/0347]Executive Summary of the ImpactAssessment [SWD/2019/0348]Amended by (EU) 2021/341
Household refrigerating appliances	<u>(EU) 2019/2016</u> Amended by <u>(EU) 2021/340</u>	(EU) 2019/2019Impact Assessment[SWD/2019/0341]Executive Summary of the ImpactAssessment [SWD/2019/0342]Amended by (EU) 2021/341
Household tumble driers	(EU) No 392/2012 Harmonised standards: <u>2014/C</u> <u>149/01</u>	(EU) No 932/2012Impact Assessment [SWD(2012) 289]Executive Summary of the ImpactAssessment [SWD(2012) 290]Harmonised standards: 2014/C149/01
Household washing machines and washer-dryers	(EU) 2019/2014 Amended by <u>(EU) 2021/340</u>	EU) 2019/2023Impact Assessment[SWD/2019/0349]Executive Summary of the ImpactAssessment [SWD/2019/0351]Amended by (EU) 2021/341
Local space heaters	(EU) 2015/1186 Transitional methods of measurement and calculation: 2017/C 076/02 Guidelines – November 2017	(EU) 2015/1188Impact Assessment [SWD(2015) 90]Executive Summary of the ImpactAssessment [SWD(2015) 91]Transitional methods ofmeasurement and calculation:2017/C 076/02Guidelines – November 2017

Product groups	Energy labelling legislation	Ecodesign legislation
Local space heaters (cont.)		(EU) 2015/1185 Transitional methods of measurement and calculation: 2017/C 076/02 Guidelines – November 2017
Professional refrigerated storage cabinets	<ul> <li>(EU) 2015/1094</li> <li>Transitional methods of measurement and calculation: 2017/C 044/01</li> <li>FAQ – April 2018</li> </ul>	(EU) 2015/1095Impact Assessment [SWD(2015) 97]Executive Summary of the Impact Assessment [SWD(2015) 96]Transitional methods of measurement and calculation: 2017/C 044/01FAQ - April 2018
Residential ventilation units	(EU) No 1254/2014 Transitional methods of measurement and calculation: <u>2016/C 416/06</u> Mandate M/537 : <u>C(2015) 8325</u> <u>Guidelines – October 2016</u>	(EU) No 1253/2014Impact Assessment [SWD(2014) 222]Executive Summary of the Impact Assessment [SWD(2014) 223]Transitional methods of measurement and calculation: 2016/C 416/06Mandate M/537: C(2015) 8325 Guidelines – October 2016
Solid fuel boilers and packages of a solid fuel boiler, supplementary heaters, temperature controls and solar devices	(EU) 2015/1187 Transitional methods of measurement and calculation: 2017/C 076/01 Guidelines - 2018 Mandate M/551: C(2016) 7764	(EU) 2015/1189Impact Assessment [SWD(2015) 92]Executive Summary of the Impact Assessment [SWD(2015) 93]Guidelines - 2018Mandate M/551: C(2016) 7764
Space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device	(EU) No 811/2013Transitional methods of measurement and calculation: 2014/C 207/02Tool for calculating the energy efficiency of packages of space, water and combination heatersMandate M/535: C(2015)2626 Guidelines – 2018	(EU) No 813/2013Impact Assessment [SWD(2013) 297]Executive Summary of the ImpactAssessment [SWD(2013) 296]Transitional methods ofmeasurement and calculation:2014/C 207/02Mandate M/535: C(2015)2626Guidelines - 2018
Electronic displays and televisions	(EU) 2019/2013 Amended by (EU) 2021/340	(EU) 2019/2021 Impact Assessment [SWD/2019/0354] Executive Summary of the Impact Assessment [SWD/2019/0355]
Vacuum cleaners		Amended by (EU) 2021/341(EU) No 666/2013Impact Assessment [SWD(2013) 240]Executive Summary of the Impact Assessment [SWD(2013) 241]Harmonised standards: 2017/C 267/02267/02Mandate M/540: C(2015)8733 Guidelines – September 2014

Product groups	Energy labelling legislation	Ecodesign legislation
Water heaters, hot water storage tanks and packages of water heater and solar device	<ul> <li>(EU) No 812/2013</li> <li>Transitional methods of measurement and calculation: 2014/C 207/03</li> <li>Mandate M/534: C(2015)2625</li> <li>Tool for calculating the energy efficiency of packages of space, water and combination heaters</li> <li>Guidelines - 2018</li> </ul>	<ul> <li>(EU) No 814/2013</li> <li>Impact Assessment [SWD(2013) 295]</li> <li>Executive Summary of the Impact Assessment [SWD(2013) 294]</li> <li>Transitional methods of measurement and calculation: 2014/C 207/03</li> <li>Mandate M/534: C(2015)2625</li> <li>Guidelines - 2018</li> </ul>
Air heating products, cooling products, high temperature process chillers and fan coil units	N/A *	(EU) 2016/2281Impact Assessment [SWD(2016)422]Executive Summary of the ImpactAssessment [SWD(2016)421]Guidelines – July 2018
Circulators (glandless standalone circulators and glandless circulators integrated in products)	N/A	(EC) No 641/2009 Impact Assessment Part 1 [SEC(2009) 1016] Impact Assessment Part 2 Impact Assessment Part 3 Impact Assessment Part 4 Impact Assessment Summary [SEC(2009) 1017] Amended by (EU) No 622/2012 and by (EU) 2019/1781
Computers and computer servers	N/A	<pre>(EU) No 617/2013 Impact Assessment [SWD(2013) 219] Executive Summary of the Impact Assessment [SWD(2013) 218] Guidelines - June 2014 (EU) 2019/424 (servers and data storage products) Impact Assessment [SWD/2019/0106] Executive Summary of the Impact Assessment [SWD/2019/0105]</pre>
Electric motors	N/A	(EC) No 640/2009   Impact Assessment [SEC(2009) 1013]   Impact Assessment Summary [SEC(2009) 1014]   Guidelines – December 2014 Amended by (EU) No 4/2014 Repealed by (EU) 2019/1781 – in application from 1 July 2021   Impact Assessment [SWD/2019/0343]

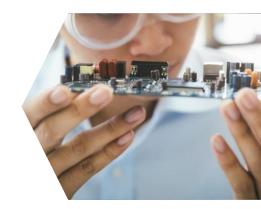
Product groups	Energy labelling legislation	Ecodesign legislation
Electric motors (cont.)		Executive Summary of the Impact Assessment [SWD/2019/0344]
		Amended by <u>(EU) 2021/341</u>
External power supplies (no- load condition electric power consumption and average active efficiency of external power supplies)	N/A	(EU) 2019/1782 Impact Assessment [SWD/2019/0345] Executive Summary of the Impact Assessment [SWD/2019/0346]
Fans driven by motors with an electric input power between 125 W and 500 kW	N/A	(EU) No 327/2011Impact Assessment [SEC(2011) 384]Impact Assessment Summary[SEC(2011) 385]
Simple set-top boxes	N/A	(EC) No 107/2009Impact Assessment [SEC(2009) 114]Impact AssessmentSummary[SEC(2009) 113]
Small, medium and large power transformers	N/A	(EU) No 548/2014Impact Assessment [SWD(2014) 162]Executive Summary of the Impact Assessment [SWD(2014) 161]Amended by (EU) 2019/1783Impact Assessment [SWD/2019/0306]
Standby and off mode electric power consumption of electrical and electronic household and office equipment	N/A	(EC) No 1275 /2008,Amended by (EU) No 801/2013Impact Assessment [SWD(2013) 306]Executive Summary of the ImpactAssessment [SWD(2013) 305]Guidelines – November 2014and by (EU) 2019/2021
Water pumps	N/A	(EU) No 547/2012Impact Assessment [SEC(2012) 178]Executive Summary of the ImpactAssessment [SEC(2012) 179]
Welding equipment	N/A	(EU) 2019/1784Impact Assessment[SWD/2019/0340]Executive Summary of the ImpactAssessment [SWD/2019/0339]
Refrigerating appliances with a direct sales function	(EU) 2019/2018 Amended by (EU) 2021/340	(EU) 2019/2024 Impact Assessment [SWD/2019/0352] Executive Summary of the Impact Assessment [SWD/2019/0353] Amended by (EU) 2021/341

#### 3.3.1. Ecodesign requirements

The *Ecodesign Directive* sets the general framework and is complemented by various Commission regulations, each focusing on a different product group. Exporters of electronic equipment from the Philippines to the EU must follow the relevant Ecodesign regulations that apply to the relevant product group.

# Management system for assessing conformity

Annex V to the *Ecodesign Directive* requires manufacturers to respect certain environmental aspects related to product performance and energy consumption. This requires implementing specific measures during the design and manufacturing stage, which must be documented in a systematic way, in form of a management system to show that the products comply with the *Ecodesign Directive*.



The following elements must be included in the management system for conformity assessment:

- 1) Environmental product performance policy;
- 2) Ecological profile of the product;

3) Tests for product performance against environmental indicators;

4) Relevant environmental assessment; and

5) Specifications that indicate the applicable standards.

# Technical documentation, CE marking, and EC declaration of conformity

Article 4 of the *Ecodesign Directive* requires importers to keep and make available the EC Declaration of Conformity, which is the declaration where "*the manufacturer or its authorised representative ensures and declares that the product complies with all relevant provisions of the applicable implementing measure*",<sup>102</sup> and the technical documentation. Exporters of electronic and electrical products from the Philippines to the EU should ensure that products contain a CE marking as shown in Annex III to the *Ecodesign Directive* and comply with the EC declaration of conformity as shown in Annex VI to the *Ecodesign Directive*. Exporters should ensure that they possess the following technical documentation listed in Annex IV of the Ecodesign Directive:

"(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) elements of the product design specification relating to environmental design aspects of the product;

(e) a list of the appropriate standards referred to in Article 10, 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 Article 10 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; 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".<sup>103</sup>

# 3.3.2. Energy Labelling requirements

The EU's **energy labelling requirements** are **complementary** to the *Ecodesign Directive*. Similar to the *Ecodesign Directive*, the *Energy Labelling Regulation* sets a general framework that includes several sub-regulations, each one focusing on a

#### **Energy Label Generator and consumer information**

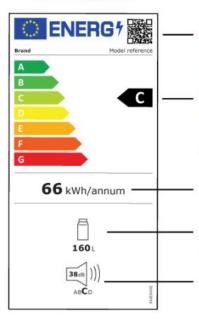
The EU provides an online tool called '*Energy Label Generator*' that allows manufacturers to generate their own energy label for products deriving from the regulations adopted before 2016.<sup>105</sup> Since 1 March 2021, the EU applies a new A to G energy scale for fridges, dishwashers, washing machines, and televisions. The European Commission notes that, in addition to these 4 product groups, the energy labels for light sources, such as light bulbs, were rescaled from 1 September 2021 and that other product groups would follow.<sup>106</sup>

In addition, the European Commission has developed information tools to help consumers, retailers, and manufacturers in the transition from the old to the new labels. One of this information tools is the *European*  different product group. Exporters of electronic equipment from the Philippines to the EU must follow the relevant energy labelling regulations that apply to the relevant product group and affix a compliant energy label on the products and/or its packaging.<sup>104</sup>

*Product Registry for Energy Labelling (EPREL)*, which allow consumers to directly access information for specific products by scanning the QR code include in the new energy labels.<sup>107</sup> Since 1 January 2019, suppliers (*i.e.*, manufacturers, importers, or authorised representatives) established in the EU "*must register their products required to have an EU energy label in the EPREL database before placing them on the EU market*".<sup>108</sup> If manufacturers are established in third countries, such as in the Philippines, they will need an importer or a legal representative established in an EU Member State to register their products in the EPREL.

Manufacturers can find more information on the EU's energy labelling rescaling and transition periods in an EU summary document.<sup>109</sup>

Figure 9: An example of the EU's energy label for a fridge without a freezer



#### New energy label

The QR code gives access to more information on the model

# **The rescaled energy efficiency class** for this fridge, an A+++

in the previous label

# The annual energy consumption of this fridge is calculated with refined methods

**The volume** of the fridge expressed in liters (L)

**The noise level** measured in decibels (dB) and using a four classes scale

# 3.3.3. Reparability

The EU is currently discussing legislative initiatives to review the EU's *Ecodesign Directive* covering electronic products, such as washing machines, dishwashers, fridges, electronic displays (televisions and monitors), and lamps with the objective to introduce new requirements, such as making spare parts more easily replaceable, and ensuring that key parts and repair and maintenance information are available for end users and professional repairers as appropriate, for a minimum duration of 7 to 10 years, depending on the product.<sup>110</sup>

The EU is currently discussing the following initiatives:

Proposal for a Directive of the European Parliament and of the Council amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and better information;<sup>111</sup> and

Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC.<sup>112</sup>

These legislative initiatives should be monitored by exporters of electronic equipment from the Philippines to the EU, as their adoption would lead to new requirements.

# 3.3.4. The proposed new Ecodesign for Sustainable Products Regulation

On 30 March 2022, the European Commission proposed a new *Ecodesign for Sustainable Products Regulation*<sup>113</sup> for more environmentally sustainable and circular products. It was published together with the *Ecodesign and energy labelling working plan 2022-2024*,<sup>114</sup> which covers "*new energy-related products and updates and increases the ambition for products that are already regulated, as a transitionary measure until the new regulation enters into force. It addresses consumer electronics, such as smartphones, tablets and solar panels, the fastest-growing waste stream*".<sup>115</sup>

The European Commission notes that the proposal for a new Ecodesign for Sustainable Products Regulation "builds on the existing Ecodesign Directive, which currently only covers energy-related products". <sup>116</sup> The proposed new Ecodesign for Sustainable Products Regulation would establish "a framework to set ecodesign requirements for specific product groups to significantly improve their circularity, enerav performance and other environmental sustainability aspects" and it would "enable the setting of performance and information requirements for almost all categories of physical goods placed on the EU market".117

The proposed rules would allow for the setting of a wide range of requirements, including on:

- product durability, reusability, upgradability and reparability
- presence of substances that inhibit circularity
- energy and resource efficiency
- recycled content
- remanufacturing and recycling
- carbon and environmental footprints
- information requirements, including a Digital Product Passport

The proposed information requirements to be set out in the "Digital Product Passport" are intended to "provide information about products' environmental sustainability", with the objective to "help consumers and businesses make informed choices when purchasing products, facilitate repairs and recycling and improve transparency about products' life cycle impacts on the environment" as well as assist "public authorities to better perform checks and controls".

Exporters of electronic equipment from the Philippines to the EU should follow the developments regarding the *Ecodesign for Sustainable Products Regulation* and prepare for compliance with the forthcoming rules.



# 3.4. Equipment for Explosive Atmospheres (ATEX) Directive

All equipment and protective systems intended for use in potentially explosive atmospheres must meet standardisation mandates and harmonised technical specifications before being placed on the EU market. *Directive 2014/34/EU*<sup>118</sup> provides the essential requirements that equipment and protective systems intended for use in potentially explosive atmospheres must meet before being placed on the EU market.

# 3.5. Radio Equipment Directive (RED)

The *Radio Equipment Directive* (RED)<sup>119</sup> establishes a framework that regulates the placement of radio equipment on the EU market. The *Radio Equipment Directive* sets out the essential requirements, such as regarding the safety of individuals, domestic animals and property, electromagnetic compatibility, and efficient use of the radio spectrum. The *Radio Equipment Directive* also provides the basis for further regulation governing certain additional aspects, such as technical features for the protection of privacy and personal data, as well as against fraud. Additional rules concern interoperability, access to emergency services, and compliance regarding the combination of radio equipment and software.

Article 2 of the *Radio Equipment Directive* defines 'radio equipment' as "an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination and/or radiodetermination.<sup>120</sup> Therefore, the *Radio Equipment Directive* is applicable to the wide range of electronic products that are Wi-Fi, Bluetooth, LTE, 5G, or GPS enabled.

# 3.5.1. Product scope

The *Radio Equipment Directive* covers radio equipment operating at frequencies below 3,000 GHz,<sup>121</sup> such as wireless earphones, smartphones, smartwatches, fitness trackers, and GPS navigation devices. Exporters of radio equipment can find information on equipment not covered by the *Radio Equipment Directive* in Annex 1 to the *Radio Equipment Directive*.

## 3.5.2. Essential requirements

Exporters of radio equipment from the Philippines to the EU should ensure that the equipment is manufactured according to the essential requirements provided in Article 3 of the *Radio Equipment Directive*, namely:

# " 1. Radio equipment shall be constructed so as to ensure:

(a) the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying; and

(b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

2. Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

3. Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:

(a) radio equipment interworks with accessories, in particular with common chargers;

(b) radio equipment interworks via networks with other radio equipment;

(c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;

(d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;

*(f) radio equipment supports certain features ensuring protection from fraud;* 

(g) radio equipment supports certain features ensuring access to emergency services; (h) radio equipment supports certain features in order to facilitate its use by users with a disability; and

(i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated."

# 3.5.3. Obligations of economic operators and conformity assessment procedures

Exporters of radio equipment from the Philippines to the EU can find information on the obligations of manufacturers, authorised representatives, importers, and distributors in Articles 10,11,12,13, and 14 of the *Radio Equipment Directive*. Article 12 of the *Radio Equipment Directive* states that EU importers must ensure that manufacturers comply with the appropriate conformity assessment procedure referred to in Article 17. Additionally, manufacturers in third countries must ensure that the radio equipment contains the CE marking and that the product is accompanied by the information required under Article 10(2) and 10(6) to (10).

The obligations included in article 10(2) and (6) to (10) are the following:<sup>122</sup>

## Article 10(2):

" radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum";

#### Article 10(6) to (10):

- The radio equipment must have a type, batch or serial number or other element allowing its identification either on the packaging or in a document accompanying the radio;
- The radio equipment should indicate the name of the manufacturer, registered trade name or registered trade mark and the postal address at which they can be contacted. When this information cannot be included on the equipment or packaging it should be contained in a document accompanying the product;
- The radio equipment must be accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users;
- Radio equipment intentionally emitting radio waves should contain the following information on its case: "(a) frequency band(s) in which the radio equipment operates; and (b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates";
- Each item of radio equipment must be accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity; and
- The product must contain information available on the packaging to allow "the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist". Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

Exporters should ensure that the technical documentation complies with the contents listed in Annex V to the *Radio Equipment Directive*. Exporters of radio equipment should take note of the conformity assessment procedures set out in Annexes II, III, and IV to the *Radio Equipment Directive*. As part of the

conformity assessment with provisions of the *Radio Equipment Directive*, manufacturers or the authorised representative must prepare an EU declaration of conformity in compliance with the models presented in Annexes VI and VII to the *Radio Equipment Directive*.

For further information on the Radio Equipment Directive, the European Commission provides the following
resources: <sup>123</sup>

Information on:	Link
Delegated and implementing acts under the RED	<ul> <li><u>Commission Delegated Regulation (EU) 2022/30</u> of 29 October 2021</li> <li>supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive</li> <li><u>Commission Delegated Regulation (EU) 2019/320</u> of 12 December 2018 with regard to the application of the essential requirements referred to in Article 3(3)(g) of Directive 2014/53/EU in order to ensure caller location in emergency communications from mobile devices</li> <li><u>Commission Implementing Regulation (EU) 2017/1354</u> specifies how to present the information provided for in Article 10(10) of Directive 2014/53/EU</li> <li>Download the <u>high-resolution pictogram</u> (described in Commission Implementing Regulation 2017/1354 - Article 10(10) of Radio Equipment Directive 2014/53/EU) - for printed product documentation</li> </ul>
Guidance	The RED guide aims to help with the common application of the RED.         Radio equipment directive FAQ: relates to the transition between the R&TTED and the RED         See also:         - Subclasses: class 1 equipment – from January 2020 (January 2020 version of indicative and non-exhaustive list)         - Subclasses: class 1 equipment – January 2018 until 31 December 2019 (January 2018 version of indicative and non-exhaustive list)         - Subclasses: class 1 equipment - January 2018 until 31 December 2019 (January 2018 version of indicative and non-exhaustive list)         - Subclasses: class 1 equipment - October 2016 until 31 December 2017 (October 2016 version of indicative and non-exhaustive list) - please note that in this document, some references to old Commission decisions or harmonised standards should read as references to the most recent Commission decisions or harmonised standards         - Notification of draft interface regulations
Standardisation	Harmonised standards under the RED           Voluntary harmonised standards in support of the RED have been and are being prepared by CENELEC and ETSI in reply to the standardisation request           M/536
Notified bodies	Notified bodies relating to the RED
Contact points	Market surveillance authorities Spectrum authorities

# 3.6. Battery Directive

The EU's *Battery Directive*<sup>124</sup> provides importers and manufacturers with rules regarding batteries and accumulators. The *Battery Directive* seeks to contribute to the protection, preservation, and improvement of

the quality of the environment by minimising the negative impact of batteries and accumulators and waste batteries and accumulators.<sup>125</sup>

# 3.6.1. Product scope

Article 2 provides that the *Battery Directive* applies to all types of batteries and accumulators, regardless of their shape, volume, weight, material composition, or use. Products covered by the *Battery Directive* include batteries and accumulators, such as alkaline batteries, button-cell batteries, lithium-ion batteries, lithium metal batteries, nickel cadmium batteries, nickel metal hydride batteries, and sealed lead-acid batteries.

# 3.6.2. Substance restrictions

Article 4 of the *Battery Directive* prohibits the placing on the EU market of:

- All batteries or accumulators, whether or not incorporated into appliances, that contain more than 0,0005 % of mercury by weight; and
- Portable batteries or accumulators, including those incorporated into appliances, that contain more than 0,002 % of cadmium by weight.

# 3.6.3. Labelling requirements

Exporters of batteries and accumulators should comply with the labelling requirements set out in Article 21 of the *Battery Directive*, and affix to their products, the symbol provided in Annex II to the *Battery Directive*. Exporters of batteries and accumulators can find more information on exempted batteries and accumulators in Article 4 of the *Battery Directive*, such as exemptions for portable batteries and accumulators intended for use in emergency and alarm systems and medical equipment.

Figure 10: Annex II to the Battery Directive provides the symbol for batteries, accumulators and battery packs for separate collection





# 3.6.4. Registration requirements

Article 17 of the *Battery Directive* requires producers to register according to procedural requirements in each EU Member State in accordance with Annex IV to the *Battery Directive*, and provides details on the following:

- The requirements for registration;
- The information to be provided by the producers; The registration fee;
  - Change of registration data; and
- The deregistration procedure.

# 3.6.5. Proposed new EU Battery law

On 10 December 2022, the European Commission published the Proposal for a *Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020*<sup>126</sup>, which aims at ensuring "*that batteries placed in the EU market are sustainable and safe throughout their entire life cycle*".

The proposed Regulation would establish *"requirements on sustainability, safety, labelling and information to allow the placing on the market or putting into service of batteries, as well as requirements for the collection, treatment and recycling of waste batteries"*.<sup>127</sup>

Regarding the scope, Article 1 of the proposed Regulation notes that the new rules would apply "to all batteries, namely portable batteries, automotive batteries, electric vehicle batteries and industrial batteries, regardless of their shape, volume, weight, design, material composition, use or purpose. It shall also apply to batteries incorporated in or added to other products". With respect to sustainability, safety, labelling and information requirements for batteries, Article 4 of the Proposed Regulation provides that:

" 1. Batteries shall only be placed on the market or put into service if they meet:

(a) the sustainability and safety requirements set out in Chapter II;

*(b) the labelling and information requirements set out Chapter III.* 

2. For any aspects not covered by Chapters II and III, batteries shall not present a risk to human health, to safety, to property or to the environment."

Exporters of batteries or of products containing batteries from the Philippines to the EU should carefully consider the proposed new EU rules on batteries and follow the developments on the proposed Regulation and prepare for compliance.



# 3.7. Electronic Toys: Toy Safety Directive

Exporters of electronic toys from the Philippines to the EU must comply with the EU *Toy Safety Directive*,<sup>128</sup> which aims at ensuring that *"toys meet safety requirements that are amongst the strictest in the world, especially in relation to the use of chemicals in toys"*.

# 3.7.1. Product scope

Article 2 of the *Toy Safety Directive* provides that the rules "*apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys).*"

According to Article 2 of the *Toy Safety Directive*, the Directive does not apply to the following toys:

*"(a) playground equipment intended for public use; (b) automatic playing machines, whether coin operated or not, intended for public use;*  The EU's *Toy Safety Directive* lays down essential safety requirements relating to:

General risks: the health and safety of children, as well as other people such as parents or caregivers
 Particular risks: physical and mechanical, flammability, chemical, electrical, hygiene and radioactivity risks

*(c) toy vehicles equipped with combustion engines; (d) toy steam engines; and (e) slings and catapults*".

Additionally, Annex I of the *Toy Safety Directive* includes a list of products not considered as toys under this Directive, such as decorative objects for festivities and celebrations and sport equipment including roller skates.

#### 3.7.2. Obligations of manufacturers

Article 4 of the *Toy Safety Directive* requires manufacturers to:

- Design and manufacture the toys in accordance with the essential requirements set out in Article 10 and Annex II, referring to physical and mechanical properties, flammability, chemical properties, electrical properties;
- Draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19;
- Draw up an EC declaration of conformity, as referred to in Article 15, and affix the CE marking, as set out in Article 17(1);
- Keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market; and
- Ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

Exporters of toys from the Philippines to the EU can find further information on the obligations for

manufacturers, authorised representatives, importers, and distributors in Articles 4 to 8 of the *Toy Safety Directive*.

Exporters and manufacturers from the Philippines must comply with the following obligations:

- The manufacturer must carry out the appropriate conformity assessment; and
- Provide all technical documentation of the product and ensure that the toy contains the required conformity marking and is accompanying by the required documents:
  - The toys must contain a type, batch, serial or model number or other element allowing their identification; and
  - The toy must indicate the name of the manufacturer, registered trade name or registered trademark and the address at which they can be contacted on the toy or, on its packaging or in a document accompanying the toy.

Exporters of toys from the Philippines to the EU can find further information on the EC Declaration of Conformity in Annex III and warning signs in Annex V of the *Toy Safety Directive*.

# 3.7.3. Requirements relating to electrical properties of toys

Part IV of Annex II to the *Toy Safety Directive* provides for the following requirements regarding electrical properties of toys:

 Toys shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken;

- 2) Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock;
- 3) Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched;

- **4)** Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source;
- **5)** Electric toys must provide adequate protection against fire hazards;
- 6) Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy, and must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures;
- 7) Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor;
- 8) Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, lightemitting diodes (LEDs) or any other type of radiation; and
- **9)** The electrical transformer of a toy shall not be an integral part of the toy.

# **Further information**

For further information on the Toy Safety Directive, the EU provides the following:<sup>129</sup>

Information on:	Link	
Harmonised European standards	The Toy Safety Directive does not specify the technical detail of toy safety requirements. The technical details are developed by the <u>European</u> <u>Standardisation Organisations</u> (CEN, CENELEC).	
Notified bodies	Notified bodies perform EC-type examination and issue EC-type examination certificates. The EC-type examination is one of the two possible <u>conformity</u> <u>assessment</u> procedures allowing toys to be marketed in the EU. Notified bodies have been designated by EU countries.	
Voluntary agreements with stakeholders	Stakeholders have signed voluntary agreements with the European Commission to improve toy safety         Voluntary agreement between the European Commission and the Toy         Industries of Europe         Voluntary agreement between the European Commission and         Eurocommerce, the European Retail Round Table, Toy Traders of Europe and the European Promotional Products Association	

Information on:	Link
More information	The blue guide on the Implementation of EU product rulesBrochure on toy safetyToy safety tips for consumers
Contact	The Commission's toy safety experts can be contacted by <u>email</u> .

# **3.8. Health control of articles in contact with food products**

EU rules on food contact materials are set out in *Regulation (EC) No 1935/2004*.<sup>130</sup> The EU regulates food contact materials to ensure a high level of food safety.

Exporters of electronic equipment from the Philippines to the EU that is intended to come into contact directly or indirectly with foodstuffs must comply with the requirements laid down in the EU rules on food contact materials, which aims at ensuring a high level of protection of human health and of the interests of consumers.<sup>131</sup>

Exporters of food processing electronic equipment from the Philippines to the EU should ensure compliance with Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food when placed on the EU market. The regulated food contact materials include processing machines, which must be manufactured so that they do not transfer their constituents to food in quantities that could endanger human health, change the composition of the food in an unacceptable way, or deteriorate the taste and odour of foodstuffs.<sup>132</sup>

# 3.8.1. Product scope

Article 2 of *Regulation (EC) No 1935/2004* provides that the rules apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

- (a) are intended to be brought into contact with food; or
- (b) are already in contact with food and were intended for that purpose; or
- (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

According to Article 2 of *Regulation (EC) No 1935/2004*, it does not apply to materials or articles supplied as antiques, covering or coating materials, such as the materials covering prepared meal products and fixed public or private water supply equipment.

# **3.8.2.** Key Definitions

Exporters of electronic equipment should take note of the following definitions relating to '*active food contact materials and articles*' and '*intelligent food contact materials and articles*' provided in Article 2 of Regulation (EC) No 1935/2004:

" 'active food contact materials and articles' (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food";

"'intelligent food contact materials and articles' (hereinafter referred to as intelligent materials and articles) means materials and articles which monitor the condition of packaged food or the environment surrounding the food".

# 3.8.3. General requirements

Article 3 of *Regulation (EC) No 1935/2004* provides for general requirements, namely:

- Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or
  - (b) bring about an unacceptable change in the composition of the food; or
  - (c) bring about a deterioration in the organoleptic characteristics thereof.
- 2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

Exporters of electronic equipment intended to come into contact with food can find more information on the materials and articles covered by specific measures in Annex I to *Regulation (EC) No 1935/2004.* 

Exporters can find more information on special requirements for active and intelligent materials and articles, in Article 4, such as that active materials must not provide any change to the composition of the food. Additionally, Article 5 of *Regulation (EC) No 1935/2004* provides that specific measures may be adopted or

amended regarding specific groups of materials and articles. Such specific measures can include a list of substances authorised for use in the manufacturing of materials and articles, purity standards of specific substances, special conditions of use of substances, etc.

Exporters should comply with the labelling requirements set out in Article 15 and Annex II to *Regulation (EC) No 1935/2004.* 

Figure 11: Annex II to Regulation (EC) No 1935/ 2004



Exporters of electronic equipment from the Philippines to the EU should comply, in addition to *Regulation (EC) No 1935/2004*, with good manufacturing practices set out in *Commission Regulation (EC) No 2023/2006*<sup>133</sup>, and with specific EU legislation on certain materials, including on plastic and ceramics, as well as with EU Member State's legislation concerning food contact materials.



# 3.9. General Product Safety Directive

The EU requires that all products placed on the EU market must be safe for consumer use and must comply with product specific rules and standards. In case of products that fall outside the scope of specific product rules and standards, exporters must comply with the EU's *General Product Safety Directive* (hereinafter, GPSD), which outlines general product safety requirements that can apply to all products.<sup>134</sup> The GPSD aims at ensuring that products are safe in order to protect consumers' health and safety.<sup>135</sup>

Exporters of electrical and electronic equipment from the Philippines to the EU can find information on requirements relating to general safety requirement, conformity assessment criteria and European standards in Chapter II of *Directive 2001/95/EC*, and on obligations of producers and distributors in Chapter III of *Directive 2001/95/E* 

# 3.9.1. Proposed new rules on general product safety

On 30 June 2021, the European Commission published a *Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council*<sup>136</sup> with the aim to:

- Update and modernise the general framework for the safety of non-food consumer products;
- 2) Preserve its role as a safety net for consumers;
- Adapt the provisions to challenges posed by new technologies and online transactions; and
- 4) Ensure a level playing field for businesses.

Exporters of electrical and electronic equipment from the Philippines to the EU should carefully consider the proposed new EU rules on general product safety and follow the developments on the proposed Regulation.



# **PART IV:**

# Complying with domestic requirements to export to the EU

For products that are prohibited or regulated for export according to Philippine law, certain accreditations, clearances or permits are needed to export these products.<sup>137</sup> The information in this section is derived from official sources and updated as of May 2023. Exporters may refer to the relevant website/s to check for any changes that may apply.

# 4.1. Optical Media Board (OMB)<sup>138</sup>

The Optical Media Board (OMB) registers and grants licenses to establishments or entities to engage in the business of manufacturing, mastering, manufacture, replication, importation, or exportation of optical media (which fall under HS chapter 85). An OMB license is needed to obtain an export permit.<sup>139</sup>

Fees	Import/Export Permit Fee: P500/Way Bill or Bill of Lading Clearance Fee: PHP 50
Forms	OMB Application Form for Export Permit Online download: <u>https://www.omb.gov.ph/wp-</u> <u>content/uploads/2018/07/Exporter-Application-Form.pdf</u>
Contact	Address: No. 35 Scout Limbaga Street, Barangay Laging Handa, Quezon City, Philippines E-mail: <u>info@omb.gov.ph</u> Telephone: (+632) 8374.0237 Website: <u>https://www.omb.gov.ph</u>

# **Export Permit: Optical and Magnetic Media**

An Export Permit is issued by the OMB for license holders engaged in the exportation of optical media products, manufacturing equipment, parts, and accessories.

#### **Required documents**

- Application Form
- Registration/License as Importer and/or Exporter
- Affidavit of Undertaking
- Certified Copy of Contract and/or Certificate of Ownership from the Source of Rights
- Air Way Bill or Bill of Lading
- Certified Copy of Proforma Invoice
- Packing List



# Procedure

- Obtain OMB Clearance of No Administrative Case from the OMB Legal Division.
- For regular clients:
- Complete the application form online through the *Philippine National Single Window* (NSW).<sup>140</sup>
- Print form number with the corresponding bar code number.
- Submit the duly completed and notarised forms to the Registry/Receiving/Assessing Officer, then pay the required fees by presenting the Assessment Slip and payment to the Cashier.
- For new and one-time clients:
- Obtain the OMB Application Form for the Export Permit and the list of requirements from the frontline receiving/assessing area or download it online.
- Submit the duly completed and notarised application form with all required documents to the Registry Receiving/Assessing Officer for checking, then pay the required fees by presenting the Assessment Slip and payment to the Cashier.
- Claim the processed permits from the Registry Releasing Officer after five working days.

# 4.2. DTI-Strategic Trade Management Office (STMO)<sup>141</sup>

The *Republic Act No. 10697*, also known as the *Strategic Trade Management Act* (STMA),<sup>142</sup> enforces measures to prevent the proliferation of weapons of mass destruction and their means of delivery from or within the Philippines. Any person or entity that engages or intends to engage in the export, import, re-export, reassignment, transit, or transhipment of goods included in the *National Strategic Goods List* (NSGL),<sup>143</sup> which includes certain dual use electronic products, or

provides related services (such as brokering, financing, transporting in relation the movement of strategic goods between two foreign countries and providing technical assistance) is required to register with the DTI-STMO. Exporters are advised to check the NSGL and its Annexes to ascertain whether their products are covered by the STMA, and therefore need to obtain authorisation from the STMO.

# Table 9: Details of STMO Authorization

Fees	None
Contact	Address: 3F Tara Building, 389 Sen. Gil J. Puyat Ave., Makati City

# E-mail: <u>stmo@dti.gov.ph</u> Phone: (+632) 8639.0812 Website: <u>https://www.dti.gov.ph/negosyo/strategic-trade-management/</u>

Prior to engaging in the export, import, re-export, reassignment, transit, transhipment of strategic goods, or the provision of technical assistance or related services, any person must apply for an authorisation from the DTI-STMO.

There are three types of authorisations:<sup>144</sup>

- Individual authorisation: A license granted to one specific person or entity to engage in the export of strategic goods to one end-user, consignee and covering one or more strategic goods.
- 2) Global authorisation: A type of license granted to one specific person or entity to engage in the export of strategic goods to two or more specific end- users and/or in one or more countries.
- 3) General authorisation: A license to export specific strategic goods to destination countries under the conditions specified in the general authorisation. This type of authorisation may be used by STMO-registered persons if they comply with two requirements: (1) Notify the STMO before the use of such authorisation; and (2) comply with the conditions set forth therein. The STMO publishes this type of authorisation on its website.

# 4.3. Food and Drug Administration (FDA)

Apart from export permits and clearances for specific regulated products discussed in the preceding sections, businesses must note that distributors, manufacturers and traders – including exporters – of medical devices are required to apply for a License to Operate (LTO) from the Food and Drug Administration's Center for Device Regulation, Radiation Health, and Research (FDA-CDRRHR).

LTO application can be done online through the FDA eServices Portal: <u>http://eservices.fda.gov.ph</u>.<sup>145</sup>

In addition, distributors, manufacturers and traders – including exporters – of medical devices are required to secure a Certificate of Medical Device Registration (CMDR) to ensure consumer safety. Application for CPR can also be done through the FDA eServices Portal. Medical devices are classified as Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk), or Class D (high risk).<sup>146</sup>

The requirements for CMDR registration vary depending on the specific type of medical device. Exporters may check the FDA-CDRRHR webpage for more information on the detailed requirements, fees, and application process for the different medical device classes.<sup>147</sup>



# **PART V:** Further Information and Key Contacts

# 5.1. Government Departments/ Units

# 5.1.1. In the European Union

For further information on the machinery industry in the EU, the European Commission provides the following:

# Table 10: EU government authorities' websites

Information on:	Link
Machinery Sector	https://single-market- economy.ec.europa.eu/sectors/mechanical- engineering/machinery en
Directive 2006/42/EC - Guidance on the application of the essential health and safety requirements on ergonomics set out in section 1.1.6 of Annex I to the Machinery Directive 2006/42/EC	https://ec.europa.eu/docsroom/documents/9484/att achments/1/translations
List of notified bodies for Directive 2006/42/EC	https://ec.europa.eu/growth/tools- databases/nando/index.cfm?fuseaction=directive.no tifiedbody&sort=country&dir_id=131881
Guide to application of the Machinery Directive 2006/42/EC - Edition 2.2	https://ec.europa.eu/docsroom/documents/38022
Details about CE Marking	https://europa.eu/youreurope/business/product- requirements/labels-markings/ce- marking/index_en.htm
Contact points in charge of implementation and market surveillance for the Machinery Directive 2006/42/EC in EU Member States	https://ec.europa.eu/docsroom/documents/50535

# 5.1.2. In the Philippines

For any export-related queries, concerns, or request for assistance, exporters may contact the Department of Trade and Industry's Export Marketing Bureau (DTI-EMB) and Foreign Trade Service Corps (FTSC).

Institution	Description	Contact Details
Export Marketing Bureau (EMB)	EMB is mandated to oversee the development, promotion, and monitoring of Philippine exports and offers a wide variety of services and assistance programs for exporters.	Address: 1-2F DTI International Building 375 Sen. Gil J. Puyat Ave., Makati City Phone: (+632) 8465.3300 locals 102, 110 E-mail: <u>Exports@dti.gov.ph</u> Website: <u>https://www.tradelinephilippines.dti.gov.ph/</u>
Foreign Trade Service Corps (FTSC)	FTSC maintains a number of Philippine Trade and Investment Centers (PTIC) abroad that provide assistance to Philippine exporters to be able to access international markets. For market-specific concerns, exporters may contact the FTSC and the various PTIC posts in the EU.	FOREIGN TRADE SERVICE CORPS (FTSC)Address: 3F DTI International Building 375 Sen. GJ. Puyat Ave. Makati CityContact: (+632) 8465.3380E-mail: FTSC@dti.gov.phPTIC-BERLIN, GERMANYCommercial Counsellor: Nicanor S. BautistaAddress: Philippine Trade and Investment CenterEmbassy of the Philippines, Rankestr. 26, BerlinContact: +4930.8800.7719/8867.7499E-mail: Berlin@dti.gov.phPTIC-BRUSSELS, BELGIUMCommercial Counsellor: Magnolia Misolas-AshleyAddress: Philippine Trade and Investment CenterEmbassy of the Philippines, 207 Ave. Louise, Box 1BrusselsContact: +322.649.4400E-mail: Brussels@dti.gov.phPTIC-PARIS, FRANCECommercial Counsellor: Rosa Katrina V. BanzonAddress: Philippine Trade and Investment CenterEmbassy of the Philippines, 207 Ave. Louise, Box 1BrusselsContact: +322.649.4400E-mail: Brussels@dti.gov.phPTIC-PARIS, FRANCECommercial Counsellor: Rosa Katrina V. BanzonAddress: Philippine Trade and Investment CenterEmbassy of the Philippines, 19 rue de l'Amirald'Estang, Paris

# Table 11: Philippine government authorities



# 5.2. Business associations

It is useful for Philippine exporters of electrical and electronic equipment to be familiar with the following business associations.

# 5.2.1. In the European Union

For further information, businesses can refer to the following entities/institutions based in the EU:

# Table 12: EU business associations

Trade Association	Contact details
BusinessEurope Confederation of European Business	<b>Address</b> :Av. de Cortenbergh 168, 1000 Brussels, Belgium. <b>Phone</b> : +32 2 237 65 11 <b>E-mail</b> : main@businesseurope.eu
Orgalim Representing Europe's technology industry	Address: Orgalim – Europe's Technology Industries, BluePoint Brussels Boulevard Auguste Reyers, 80 1030 Brussels Phone: +32 2 206 68 83 E-mail: secretariat@orgalim.eu
<b>ESIA</b> The European Semiconductor Industry Association	Address: 11-13 rue de la Duchesse, 1150 Brussels Belgium Phone.: +32-2-290-36-60 E-mail: Director General Hendrik Abma, hendrik.abma@eusemiconductors.eu

# 5.2.2. In the Philippines

It is useful for Philippine exporters of electronics and electrical machinery to be familiar with the following business associations:

## Table 13: Philippine business associations

# **General Business Organizations**

Institution	Description	Contact Details
European Chamber of Commerce of the Philippines (ECCP)	ECCP is a bilateral foreign chamber offering a wide business network and business support services to promote Philippine-European business relations.	Address: 19th Floor, Philippine AXA Life Centre, Sen. Gil J. Puyat Avenue cor. Tindalo St., Makati City, 1200 Metro Manila, Philippines Contact: (+632) 8845.1323, (+632) 8856.0423 E-mail: info@eccp.com Website: https://www.eccp.com/
Federation of Philippine Industries (FPI) Federation of	FPI is a multi-sectoral umbrella organization for Philippine businesses.	Address: Unit 701 Atlanta Centre Condominium #31 Annapolis St., Greenhills, San Juan City Contact: (+632) 8722.3409, (+632) 8584.9642, (+632) 8727.4359 E-mail: fpi@fpi.ph, fpi@philonline.com, info@fpi.ph, fpi.secretariat@gmail.com
Philippine Industries (FPI)		Website: www.fpi.ph

Philippine Chamber of Commerce and Industry (PCCI)	PCCI is one of the leading umbrella business organization in the Philippines.	Address: 3F Commerce and Industry Plaza, 1030 Campus Ave. cor. Park Ave. McKinley Town Center, Fort Bonifacio, Taguig City Contact: (+632) 8846.8619 E-mail: secretariat@philippinechamber.com Website: www.philippinechamber.com
Philippine Exporters Confederation, Inc. (PHILEXPORT)	PHILEXPORT is an umbrella organization of Philippine exporters. It serves as an important government partner and provides business services for exporters.	Address: ITC Complex Roxas Boulevard, cor Sen. Gil J. Puyat Ave, 1300 Pasay Contact: (+632) 8230.5555, (+632) 8935.1025, (+632) 8782.9847 Mobile: (+63) 919.0734992, (+63) 917.7183966 E-mail: communications@philexport.ph Website: www.philexport.ph

# **Specific Industry Associations**

Institution	Description	Contact Details
Electronics Industries Association of the Philippines, Inc. (EIAPI)	EIAPI promotes the development of the local electronics industry and serves as a liaison between the industry and the government, academe, and related industries in the country.	Address: EPDC Bldg., Gen. Santos Ave. Bicutan, Taguig City Contact: (+632) 8584.2011, (+632) 8861.7565 Mobile: (+63) 998.7924033 E-mail: info@eiapi.org.ph Website: https://eiapi.org.ph/
Federation Of Electrical and Electronics Suppliers and Manufacturers of the Philippines, Inc. (PESA)	PESA is a business organization promoting the interests of electrical and electronics manufacturers in the country.	Address: PESA Bldg., 3001 R. Magsaysay Boulevard corner M. dela Fuente St. Sta. Mesa, Manila Contact: (+632) 8715.3004, (+632) 8715.3184
Semiconductor And Electronics Industries in the Philippines, Inc. (SEIPI)	SEIPI is the leading organization of multinational and local semi- conductor and electronics companies in the Philippines.	Address: 2/F Building 2, Gruppo EMS, Inc., 117-A Technology Avenue, LTI, Biñan City, Laguna Mobile: (+63) 917.8012522, (+63) 939.9884368 E-mail: helpdesk@seipi.org.oh, dclachica@seipi.org.ph Website: www.seipi.org.ph



# **ENDNOTES**

<sup>1</sup> 2021 Eurostat data; 2021 ITC Trademap data.

<sup>4</sup> <u>https://psa.gov.ph/content/highlights-2021-annual-final-international-merchandise-trade-statistics-philippines</u> (accessed 4 November 2022).

<sup>5</sup> PSA.

<sup>6</sup> Access2Markets, EU trade statistics (excluding United Kingdom), European Commission, available at <u>https://trade.ec.europa.eu/access-to-markets/en/statistics</u> (accessed 4 November 2022).

<sup>7</sup> Trade Map, ITC, available at

https://www.trademap.org/Country\_SelProductCountry.aspx?nvpm=1%7c608%7c%7c%7c%7c85%7c%7c%7c2%7c 1%7c1%7c2%7c1%7c1%7c2%7c1%7c1%7c1 (accessed 4 November 2022).

<sup>8</sup> ITC Export Potential Analysis, p. 12.

<sup>9</sup> ITC Export Potential Map – Philippines, available at <u>https://exportpotential.intracen.org/en/products/tree-map?fromMarker=i&exporter=608&toMarker=w&market=w&whatMarker=k</u> (accessed 4 November 2022).

<sup>10</sup> ITC Export Potential Analysis, p. 38.

<sup>11</sup> ITC Export Potential Analysis, p. 39.

<sup>12</sup> Eurostat, available at International trade and production of high-tech products, available at <u>https://ec.europa.eu</u> /eurostat/statistics%2Dexplained/index.php?title=Production\_and\_international\_trade\_in\_high-

tech products&oldid=561185 (accessed 4 November 2022).

<sup>13</sup> ITC Export Potential Analysis.

<sup>14</sup> Available at <u>https://gsphub.eu/country-info/Philippines</u> (accessed 4 November 2022).

<sup>15</sup> Eurostat.

<sup>16</sup> EU TPR Secretariat Report, p. 64. Regulation (EU) No. 978/2012, Annex IX.

<sup>17</sup> See Article 12 and Annex IX of the GSP Regulation, available at <u>https://eur-lex.europa.eu/legal-content/EN/</u> <u>TXT/PDF/?uri=CELEX:02012R0978-20220101&from=EN</u> (accessed 4 November 2022).

<sup>18</sup> Article 33 of the GSP Regulation.

<sup>19</sup> Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code, OJ L 343, 29.12.2015, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:</u> 02015R2446-20220101&from=EN (accessed 4 November 2022).

<sup>20</sup> Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code, OJ L 343, 29.12.2015, p. 1–706, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02015R2446-20220101&from=EN</u> (accessed 4 November 2022).

<sup>21</sup> Article 53 of Commission Delegated Regulation (EU) 2015/2446.

<sup>22</sup> Article 37 of Commission Delegated Regulation (EU) No 2015/2446.

<sup>23</sup> Laid down in Article 55 of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015, available at <u>http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L .2015.343.01.0001.01.ENG</u> (accessed 4 November 2022), which provides that:

"Regional cumulation shall apply to the following four separate regional groups:

(a) group I: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar/Burma, Philippines, Thailand, Vietnam;

(b) group II: Bolivia, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Peru, Venezuela;

(c) group III: Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, Sri Lanka;

(d) group IV: Argentina, Brazil, Paraguay and Uruguay".

<sup>24</sup> Article 55 of Commission Delegated Regulation (EU) 2015/2446.

<sup>25</sup> Article 55(1)(a) of Commission Delegated Regulation (EU) 2015/2446.

<sup>26</sup> Article 56 of Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015.

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<sup>&</sup>lt;sup>2</sup> See <u>https://industry.gov.ph/industry/electronics/</u> (accessed 4 November 2022).

<sup>&</sup>lt;sup>3</sup> See <u>https://industry.gov.ph/exports-by-major-sector-goods/</u> and <u>https://industry.gov.ph/industry/electronics/</u> (accessed 4 November 2022).

<sup>27</sup> See Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff, available at <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31987R2658</u>. The information is also provided in the EU's Access2Martkets database at <u>https://trade.ec.europa.eu/access-to-markets/en/home</u> (accessed 4 November 2022).

<sup>28</sup> See <u>https://ec.europa.eu/trade/policy/countries-and-regions/negotiations-and-agreements/</u> (accessed 4 November 2022) for the list of Agreements maintained by the EU.

<sup>29</sup> Article 55(5) and (6) of Commission Delegated Regulation (EU) 2015/2446.

<sup>30</sup> Article 47(1) of Commission Delegated Regulation (EU) 2015/2446.

<sup>31</sup> See <u>https://trade.ec.europa.eu/access-to-markets/en/content/generalised-scheme-preferences-gsp</u> (accessed 20 January 2023).

<sup>32</sup> Article 64(6) of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code OJ L 269, 10.10.201, available at <u>http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0952</u> (accessed 4 November 2022).

<sup>33</sup> Annex III to Directive 2006/42/EC.

<sup>34</sup> EU Commission – Notified bodies, available at <u>https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies en</u> (accessed 4 November 2022).

<sup>35</sup> The list is available at <u>https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.</u> notifiedbody&dir id=131881 (accessed 4 November 2022).

<sup>36</sup> OJ L-174 01/07/2011, p. 88 available at <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0065</u> (accessed 4 November 2022).

<sup>37</sup> OJ L-96, 29/03/2014, p. 79 available at <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02014 L0030-</u> 20180911 (accessed 4 November 2022).

<sup>38</sup> OJ L-96 29/03/2014, *available at*, <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0035</u> (accessed 28 July 2022).

<sup>39</sup> OJ L-169 25/06/2019, p. 1 available at <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX</u> <u>%3A32019R1020</u> (accessed 4 November 2022).

<sup>40</sup> OJ L-150 14/06/2018, p. 93 available at <u>https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02012L0019-</u> 20180704 (accessed 4 November 2022).

<sup>41</sup> OJ C-100 23/03/2021, p. 1 available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX</u> <u>%3A52021XC0323%2801%29</u> (accessed 4 November 2022).

<sup>42</sup> Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors, OJ L 162 3.7.2000, p. 1, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0014-20190726</u> (accessed 4 November 2022).

<sup>43</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), OJ L 174 1.7.2011, p. 88, available at <a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0065">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011L0065</a> (accessed 4 November 2022).

<sup>44</sup> Annex I of Directive 2011/65/EU, available at (accessed 4 November 2022).

<sup>45</sup> See Article 4(1) of Directive 2011/65/EU and Annex II to Directive 2011/65/EU.

<sup>46</sup> Annex II of Directive 2011/65/EU.

<sup>47</sup> Article 7 of Directive 2011/65/EU.

<sup>48</sup> Annex VI to Directive 2011/65/EU.

<sup>49</sup> Article 14 of Directive 2011/65/EU provides that "The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008".

<sup>50</sup> Article 7 (g) and (h) of Directive 2011/65/EU provide that.

"(g) manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;

(h) manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply".

<sup>51</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, OJ L 169, 25.6.2019, p. 1, available at <a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32019R1020">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32019R1020</a> (accessed 4 November 2022).

<sup>52</sup> Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast), OJ L 150, 14.6.2018, p. 93, available at https://eur-lex.europa.eu/legalcontent/EN/ALL/?uri=CELEX:02012L0019-20180704 (accessed 4 November 2022).

<sup>53</sup> Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312 22.11.2008, p. 3, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri= CELEX:02008L0098-20180705 (accessed 4 November 2022).

<sup>56</sup> Article 14(4) Directive 2012/19/EU.

<sup>57</sup> Article 5(d) Directive 2012/19/EU.

<sup>58</sup> Article 12 of Directive 2012/19/EU.

<sup>59</sup> Article 8 of Directive 2012/19/EU.

<sup>60</sup> Article 16 of Directive 2012/19/EU.

<sup>61</sup> Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast), OJ L 212, 22.08.2018, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02014L0030-20180911 (accessed 4 November

2022).

<sup>62</sup> Article 3(2) of Directive 2014/30/EU.

<sup>63</sup> Article 3(3) of Directive 2014/30/EU.

<sup>64</sup> Article 13 of Directive 2014/30/EU.

<sup>65</sup> The European Electrotechnical Committee for Standardization, available at https://www.cencenelec.eu/aboutcenelec/ (accessed 4 November 2022).

<sup>66</sup> The European Telecommunications Standards Institute, available at <u>https://www.etsi.org/</u> (accessed 4 November 2022).

<sup>67</sup> The European Commission, Internal Market, Industry, Entrepreneurship and SMEs, available at https://singlemarket-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/electromagneticcompatibility-emc\_en (accessed 4 November 2022).

<sup>68</sup> Article 14 of Directive 2014/30/EU.

<sup>69</sup> Article 3(1) and (2) of Directive 2014/30/EU.

<sup>70</sup> According to Article 2, of Directive 2014/30/EU, the following products are not covered by the Directive:

Electrical equipment that uses radio frequency broadcasting or receiving technologies and that are within the scope of the Radio Equipment Directive (Directive 1999/5/EC);

Radio equipment intended for use by radio amateurs;

Aeronautical products, parts, and appliances as referred to in Regulation (EC) No 216/2008;

Motor vehicles, including two or three-wheel motor vehicles;

- Medical Devices (covered by the Medical Device Regulation (EU) 2017/745);
- Marine Equipment (covered by Directive 2014/90/EU); and
- Agricultural and forestry tractors (covered by Regulation (EU) No 167/2013).

The following products are only exempted from the immunity requirements of Directive 2014/30/EU, the emission requirements still apply:

Measuring instruments (covered by Directive 2014/32/EU); and

Non-automatic weighing instruments (covered by Directive 2014/31/EU).

<sup>71</sup> Article 15 of Directive 2014/30/EU.

<sup>72</sup> Article 7 (2) of Directive 2014/30/EU.

<sup>73</sup> Article 7(3) of Directive 2014/30/EU.

<sup>74</sup> Article 17 of Directive 2014/30/EU.

<sup>75</sup> Article 17 (1) of Directive 2014/30/EU.

<sup>76</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93, OJ L 218 13.8.2008, p. 30, available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0765 (accessed 4 November 2022).

<sup>77</sup> Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, OJ L 96, 29.3.2014, p. 357-374 available at https://eur-lex.europa.eu/legalcontent/EN/ALL/?uri=CELEX%3A32014L0035 (accessed 4 November 2022).

<sup>78</sup> Article 1 of Directive 2014/35/EU.

<sup>79</sup> Article 12 of Directive 2014/35/EU.

<sup>80</sup> Available at https://www.cencenelec.eu/ (accessed 4 November 2022).

<sup>&</sup>lt;sup>54</sup> Article 3 of Directive 2012/19/EU.

<sup>&</sup>lt;sup>55</sup> Article 4 of Directive 2012/19/EU.

<sup>84</sup> Summary of references of harmonised standards published in the Official Journal – Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits, European Commission (10 May 2022), available at <a href="https://www.ibf-solutions.com/fileadmin/Dateidownloads/Amtsblaetter/2014-35-eu-low-voltage-directive-summary-list of harmonized standards add (accessed 4 Navember 2022)">https://www.ibf-solutions.com/fileadmin/Dateidownloads/Amtsblaetter/2014-35-eu-low-voltage-directive-summary-list of harmonized standards add (accessed 4 Navember 2022)</a>

summary-list-of-harmonised-standards.pdf (accessed 4 November 2022).

<sup>85</sup> European Commission, Low voltage (LVD) Directive 2014/35/EU, available at <u>https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/low-voltage-lvd en</u> (accessed 4 November 2022).

<sup>86</sup> Article 15 of Directive 2014/35/EU.

<sup>87</sup> Article 6 (2) of Directive 2014/35/EU.

<sup>88</sup> Article 6 (3) of Directive 2014/35/EU.

<sup>89</sup> See Article 6 to 10 of Directive 2014/35/EU.

<sup>90</sup> Article 17 of Directive 2014/35/EU.

<sup>91</sup> European Commission, About the energy label and ecodesign, available at <u>https://ec.europa.eu/info/energy-</u> <u>climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-</u> <u>label-and-ecodesign/about\_en#a-new-generation-of-labels</u> (accessed 4 November 2022).

<sup>92</sup> OJ L-285 31/10/2009, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0125-</u> 20121204 (accessed 4 November 2022).

<sup>93</sup> Article 1 Directive 2009/125/EC.

<sup>94</sup> OJ L 346 20.12.2016, p. 51, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:</u> <u>32016R2282&from=EN</u> (accessed 4 November 2022).

<sup>95</sup> Recital 2 Regulation (EU) 2016/2282.

<sup>96</sup> OJ L-198 28/07/2017, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R1369-</u> 20210501 (accessed 4 November 2022).

<sup>97</sup> OJ L 38, 15.2.2017, p. 1–35, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L</u>. 2017.038.01.0001.01.ENG&toc=OJ:L:2017:038:TOC (accessed 4 November 2022).

<sup>98</sup> OJ L 147, 17.5.2014, p. 1–28, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L</u>. 2014.147.01.0001.01.ENG (accessed 4 November 2022).

<sup>99</sup> OJ C 182, 2.6.2020, p. 2–3, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C</u>. 2020.182.01.0002.01.ENG&toc=OJ:C:2020:182:TOC (accessed 4 November 2022).

<sup>100</sup> European Commission, Energy, List of energy efficient products Regulations: by product group, available at <u>https://energy.ec.europa.eu/topics/energy-efficiency/energy-label-and-ecodesign/list-energy-efficient-products-regulations-product-group en#energy-labelling-legislation</u> (accessed 4 November 2022).

<sup>101</sup> List of energy efficient products Regulations: by product group, European Commission, available at <u>https://energy.ec.europa.eu/topics/energy-efficiency/energy-label-and-ecodesign/list-energy-efficient-products-regulations-product-group en#energy-labelling-legislation</u> (accessed 4 November 2022).

<sup>102</sup> Article 5(1) of Directive 2009/125/EC.

<sup>103</sup> Annex IV of Directive 2009/125/EC.

<sup>104</sup> Article 3 of Regulation (EU) 2017/1369

<sup>105</sup> European Commission, Energy Label Generator, available at <u>https://ec.europa.eu/energy/eepf-labels en</u> (accessed 4 November 2022).

<sup>106</sup> European Commission, "*In focus: The improved EU energy label – paving way for more innovative and energy efficient products*", 16 February 2021, available at <u>https://ec.europa.eu/info/news/focus-improved-eu-energy-label-paving-way-more-innovative-and-energy-efficient-products-2021-lut-16 en</u> (accessed 4 November 2022).

<sup>107</sup> European Commission, Energy Label Generator, available at <u>https://ec.europa.eu/energy/eepf-labels en</u> (accessed 4 November 2022).

<sup>108</sup> European Commission, Product database, available at <u>https://ec.europa.eu/info/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/product-database en#energy-labelling-tools (accessed 4 November 2022).</u>

<sup>109</sup> European Commission, European energy labels: rescaling and transition periods, available at <u>https://ec.europa.</u> <u>eu/info/sites/default/files/energy climate change environment/standards tools and labels/documents/rescaled e</u> <u>u energy labels and transition period.pdf</u> (accessed 4 November 2022).

<sup>110</sup> European Parliament "Right to Repair", Briefing, available at <u>https://www.europarl.europa.eu/RegData/etudes/</u> <u>BRIE/2022/698869/EPRS\_BRI(2022)698869\_EN.pdf</u> (accessed 4 November 2022).

<sup>&</sup>lt;sup>81</sup> Available at <u>https://www.iec.ch/homepage</u> (accessed 4 November 2022).

<sup>&</sup>lt;sup>82</sup> Article 13 of Directive 2014/35/EU.

<sup>&</sup>lt;sup>83</sup> Article 14 of Directive 2014/35/EU.

<sup>111</sup> Proposal for a Directive amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and better information; available at andhttps://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12467-Consumer-policy-

strengthening-the-role-of-consumers-in-the-green-transition\_en (accessed 4 November 2022).

<sup>112</sup> Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, available at <u>https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12567-Sustainable-products-initiative en</u> (accessed 4 November 2022).

<sup>113</sup> Available at <u>https://environment.ec.europa.eu/publications/proposal-ecodesign-sustainable-productsregulati</u> <u>on en</u> (accessed 4 November 2022).

<sup>114</sup> Available at <u>https://energy.ec.europa.eu/ecodesign-and-energy-labelling-working-plan-2022-2024 en</u> (accessed 4 November 2022).

<sup>115</sup> European Commission, Ecodesign for sustainable products, available at <u>https://ec.europa.eu/info/energy-</u> <u>climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-</u> <u>products/ecodesign-sustainable-products en</u> (accessed 4 November 2022).

<sup>116</sup> European Commission, Ecodesign for sustainable products, available at <u>https://ec.europa.eu/info/energy-</u> <u>climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-</u> <u>products/ecodesign-sustainable-products en</u> (accessed 4 November 2022).

<sup>117</sup> European Commission, Ecodesign for sustainable products, available at <u>https://ec.europa.eu/info/energy-</u> <u>climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-</u> <u>products/ecodesign-sustainable-products en</u> (accessed 4 November 2022).

<sup>118</sup> Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast), OJ L 96, 29.3.2014, p. 309–356, available at <a href="https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014L0034">https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014L0034</a> (accessed 4 November 2022).

<sup>119</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, OJ L 212, 22.8.2018, p. 1, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02014L0053-20180911</u> (accessed 4 November 2022).

<sup>120</sup> Article 2 of Directive 2014/53/EU.

<sup>121</sup> Article 2 of Directive 2014/53/EU.

<sup>122</sup> Article 10 of Directive 2014/53/EU.

<sup>123</sup> European Commission, Radio Equipment Directive (RED), available at <u>https://single-marketeconomy.ec.europa.</u> <u>eu/sectors/electrical-and-electronic-engineering-industries-eei/radio-equipment-directive-red en</u> (accessed 4 November 2022).

<sup>124</sup> Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, OJ L 266, 26.9.2006, p. 1, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006L0066-20180704&from=EN</u> (accessed 4 November 2022).

<sup>125</sup> Article 1 of Directive 2006/66/EC.

<sup>126</sup> Available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0798</u> (accessed 4 November 2022).

<sup>127</sup> Article 1 of the Proposed Regulation.

<sup>128</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJL 170 30.6.2009, p. 1, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009L0048-20191118</u> (accessed 4 November 2022).

<sup>129</sup> European Commission, Toy Safety in the EU, available at <u>https://single-market-economy.ec.europa.eu/</u> <u>sectors/toys/toy-safety en</u> (accessed 4 November 2022).

<sup>130</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338 13.11.2004, p. 4, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R1935-0210327</u> (accessed 4 November 2022).

<sup>131</sup> Article 1 of Regulation (EC) No 1935/2004.

<sup>132</sup> European Commission, Access2Markets, Health control of articles in contact with food products, available at <u>https://trade.ec.europa.eu/access-to-markets/en/results?product=850940&origin=PH&destination=BE</u> (accessed 4 November 2022).

<sup>133</sup> Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, OJ L 384, 29.12.2006, p.75, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R2023-20080417</u> (accessed 4 November 2022).

<sup>134</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 011, 15.1.2002, p. 4, available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX</u> <u>%3A02001L0095-20100101</u> (accessed 4 November 2022).

<sup>135</sup> Article 1 and 2 of Directive 2001/95/EC.

<sup>136</sup> Available at <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0346</u> (accessed 4 November 2022).

<sup>137</sup> The list of regulated and prohibited products as of December 2020 is available at <u>https://tradeline</u> <u>philippines.dti.gov.ph/ja/web/tradeline-portal/prohibited-and-regulated-products</u> (accessed 4 November 2022).

<sup>138</sup> 2021 OMB Citizen's Charter, available at <u>https://www.omb.gov.ph/wp-content/uploads/2021/10/CITIZEN-</u> <u>CHARTER-2021.pdf</u>, and OMB website, OMB Memorandum Circular No. 2006-006 Schedule of Fees, available at <u>https://www.omb.gov.ph/wp-content/uploads/2021/10/mc 2006-06.pdf</u> (accessed 4 November 2022).

<sup>139</sup> See 2021 OMB Citizen's Charter for the licensing procedure and requirements.

<sup>140</sup> See <u>https://nsw.gov.ph/login</u> (accessed 4 November 2022).

<sup>141</sup> DTI website, see <u>https://www.dti.gov.ph/negosyo/strategic-trade-management/</u> and <u>https://dtiwebfiles.s3.ap-southeast-1.amazonaws.com/STMO/Issuances/General+Authorization/Memorandum+Circular+No.+22-13.pdf</u> and <u>https://dtiwebfiles.s3-ap-southeast-1.amazonaws.com/Laws+and+Policies/Trade+Laws/Memorandum+Circular+No.+22-13.pdf</u>

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<sup>142</sup> Republic Act No. 10697, also known as the Strategic Trade Management Act (STMA), available at <u>https://www.officialgazette.gov.ph/2015/11/13/republic-act-no-10697/</u> (accessed 4 November 2022).

<sup>143</sup> NSGL: <u>https://www.dti.gov.ph/sdm\_downloads/national-strategic-goods-list/</u> (accessed 4 November 2022). The NSGL consists mostly of arms, ammunition, and chemicals but the Annex 2 to the also contains electronic items that are considered dual use and are thus regulated.

<sup>144</sup> See the STMO website for the authorization procedure and requirements: <u>https://dtiwebfiles.s3-ap-southeast-</u> <u>1.amazonaws.com/STMO/Publications/Registration+Guidelines.pdf</u> (accessed 4 November 2022).

<sup>145</sup> For detailed information on the requirements, fees, and process of LTO application, see <u>https://www.fda.gov.ph/</u> wp-content/uploads/2023/08/1.-Initial-Device-ESERVICES.pdf.

<sup>146</sup> See <u>https://www.fda.gov.ph/fda-circular-no-2021-017-reference-list-of-class-a-medical-devices/</u>.

<sup>147</sup> For detailed information on the CMDR requirements, fees, and process, see <u>https://www.fda.gov.ph/citizen-charter-center-for-device-regulation-radiation-health-and-research-cdrrhr/</u>.







