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EU Trade Guide

Type: Legal Guide
Law Firm: Mayer Brown LLP
Published: June 2017
Keywords: EU, Trade Law, Regulation

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Executive Summary

- The free movement of goods within the EU Customs Union entails advantages for trade into the EU: import duties only have to be paid upon first entry into the EU, custom duty rates are the same across the EU and goods can be freely circulated after they are cleared at customs.
- Goods imported into the EU are subject to a customs duty and the rate depends on the product's classification, country of origin and customs value.
- The integrated Tariff of the European Union (TARIC), is an integrated database that contains the various rules applying to specific products imported into the EU – these rules and rates can be identified using the 10 digit TARIC code assigned to imported goods.
- Goods imported into the EU are also regulated, through prohibitions and restrictions, by a combination laws and regulations implemented by various authorities. Regulatory objectives include the protection of the economy and security of the EU, safeguarding consumer health and well-being and preserving domestic plant and animal life.
- The main areas of product regulation introduced in this guide are food law and cosmetics law.
- EU food law consist of the laws, regulations and administrative provisions governing food in general, and food safety in particular. It covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals. It is adopted on the basis of scientific risk assessment under the supervision of the European Food Safety Authority (EFSA).
- Cosmetic products are harmonized under the EU Cosmetics Regulation and are directly applicable in EU Member States.

Scope

This guide provides an overview of the main principles, processes and requirements for importing goods into the European Union (the "EU") from the perspective of the trade and customs rules and the product regulatory requirements.

I. EU Trade and Customs Rules

The EU is a customs union which entails advantages for trade into the EU

The fact that the EU is a customs union means that import duties will have to be paid only once, i.e., at the time of their customs clearance into the EU. Once that is done and all import formalities have been complied with, the goods are in so-called "free circulation" in the EU. This means that they can move throughout the EU without having to settle any additional import customs duties or facing many other restrictions at their entry into any other EU Member State. Thus, goods can be cleared by way of example in the port of Amsterdam and move freely throughout the EU without other import duties being charged.

It means also that the customs duty rates are the same throughout the EU: wherever the goods are customs cleared in the EU, customs authorities must charge the same duty rate (see below the section on import duties).

Who is part of the EU?

The EU currently has 28 Member States, which are:

Austria	Italy
Belgium	Latvia
Bulgaria	Lithuania
Croatia	Luxembourg
Cyprus	Malta
Czech Republic	The Netherlands
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Spain
Hungary	Sweden
Ireland	United Kingdom

The EU Customs Union also includes the Channel Islands, the Isle of Man, Monaco and the UK Sovereign Bases in Akrotiri and Dhekelia, Cyprus.[1]

The United Kingdom has made the formal announcement that it intends to leave the EU which has triggered a 2-year process towards its departure as an EU Member State. Thus until at least 2019, but possibly longer if an extension is agreed upon, the UK should remain a member of the EU Customs Union. What the conditions will be for direct trade into the UK or for trade from the EU into the UK and *vice versa* cannot be predicted with any degree of certainty at the present time.

Entry Process

All goods imported into the EU States must be cleared by the local EU Member State's customs authorities. Centralized clearance by a single entity for goods clearing through different EU Member States is becoming possible, but subject to certain conditions whereby the importer must offer sufficient guarantees to the customs authorities of compliance with pre-defined requirements.

Goods are customs cleared by their importer or its representative. The importer does not necessarily have to be established in the EU but, as a general rule, the representative should be (with exceptions being possible). Customs clearance can be paper or electronic-based. Supporting documents must be kept by the importer and / or his representative, which will typically include the invoice for the goods.

Import Duties

Goods imported into the EU may be subject to a customs duty,[2] which is a tax collected on imports at customs clearance. The amount of customs duty owed will depend on the type of product (its classification), where the product comes from (its country of origin), and its value (its customs value).

Classification: Goods imported into the EU are subject to duty or duty-free entry in accordance with their classification under the applicable items in the Combined Nomenclature (the CN) of the EU.[3] A product's classification number, i.e., referred to as a "tariff heading", must be indicated at the time of customs clearance of the goods into the EU. The CN classifies goods by their name, use, and material used for their construction. The CN is based upon the Harmonized Commodity Description and Coding System (the

1 See: http://ec.europa.eu/taxation_customs/frequently-asked-questions/customs-2_en.

2 The normal import duty collected upon the customs clearance of the goods into the EU is usually referred to as the customs duty. Additional duties imposed, such as anti-dumping or countervailing duties (see below) are also part of the more general term of "import duties".

3 The CN is published annually, i.e. around October, to enter into force on 1 January of the following year. The CN applicable for 2017 can be found at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:294:TOC.

Harmonized System or HS), an internationally standardised system of names and numbers to classify traded products administered by the World Customs Organization. The HS has about 5,000 product groups with each group being assigned a 6-digit number. The CN further subdivides the product groups and assigns them 8-digit numbers. The 8-digit tariff subheadings set the duty rate for a product. In addition, the EU also has a so-called "TARIC",[4] which adds two digits to the 8-digit numbers of the CN to integrate all measures relating to EU customs duties, commercial and agricultural legislation.

> By integrating and coding these measures, the TARIC secures their uniform application by all Member States and gives all economic operators a clear view of all measures to be undertaken when importing into the EU or exporting goods from the EU. It also makes it possible to collect EU-wide statistics for the measures concerned.[5]

Country of Origin: Rates of duty for imported merchandise may vary depending upon the country of origin of a product. For instance, special duty rates apply to certain products from developing countries or from countries that have a free trade agreement (FTA) with the EU. There are two basic categories of rules used to determine a product's country of origin: "non-preferential" rules of origin and "preferential" rules of origin. "Non-preferential" rules generally apply to merchandise exported from countries with which the EU does not have a bilateral or multilateral FTA or to which the EU does not attribute developing country status. "Preferential" rules apply to merchandise to determine eligibility for special duty treatment under various trade agreements or duty preference programs.

The EU "non-preferential" rules of origin use the "wholly obtained" or "substantial transformation" criteria to determine the origin of an imported product. A "wholly obtained" product is entirely grown, gathered, produced or manufactured in one country. The "substantial transformation" test is applied to goods that consist in whole or in part of materials from more than one country. Under this test, the country of origin of the imported product is the last country or territory where it underwent its last, substantial, economically-justified processing or working, in an undertaking equipped for that purpose, resulting in the manufacture of a new product or representing an important stage of manufacture. For some products determined based on their tariff heading, the EU has set forth specific rules of origin that refer

4 See: http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp.
5 See: https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/taric_en.

to specific manufacturing processes or value added to be achieved to confer origin.[6]

EU "preferential" rules of origin generally use the "wholly obtained" criterion or use a tariff (sub-)heading shift method, a specific processing requirement and/or local value-content method for goods that are not wholly obtained from a country eligible for preferential duty rates. Each EU trade agreement has its own set of origin criteria that must be met. As a result, the special origin criteria must be determined by looking at the specific Origin Protocol attached to each FTA. The rules of origin to determine whether products benefit from the duty preferences granted by the EU to developing countries are set out in the EU's customs legislation.[7] [8]

Customs Value: The customs value of a product is needed to calculate the duty rate for products subject to *ad valorem* or compound duty rates (see below). The customs value is usually the price actually paid or payable for imported merchandise when sold for exportation to the EU, including the cost of transportation and insurance to the border of the EU.[9] This is referred to as the "transaction value". In certain circumstances, adjustments must be made to the transaction value or other methods of valuation must be used. For instance, it must be noted that if the services of a sales agent are being used, the commission settled to such sales agent by the seller-exporter will have to be added to the transaction value to constitute the customs value. In contrast, if the buyer-importer uses a buying agent, the commission settled to the buying agent need not be added to determine the customs value.

Duty Rates: Duty rates in the EU can be *ad valorem*, specific, or compound. An *ad valorem* duty rate is based on a percentage of the customs value of the imported merchandise. The majority of products imported to the EU are subject to *ad valorem* rates. A specific rate is a specified amount per unit of weight or quantity. A compound rate is a combination of an *ad valorem* rate and a specific rate, such as 0.5 Euros

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6 These non-preferential rules of origin can be found in Annex 22-01 to 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, of which the current text is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.343.01.0001.01.ENG&toc=OJ:L:2015:343:TOC.

7 See Annex 22-03 to the above mentioned Regulation.

8 For an overview of the EU's Generalised Scheme of Preferences or "GSP", as applicable to developing countries, including the list of countries that can benefit from the EU's GSP, see at: http://ec.europa.eu/trade/policy/countries-and-regions/development/generalised-scheme-of-preferences/.

9 This is different from the US where the cost of transportation and insurance need not be taken into account for the determination of the customs value.

per kilo plus 2 percent *ad valorem*. Non-*ad valorem* duty rates are concentrated in the agriculture sector.

Duty rates for products are found in the EU's Common Customs Tariff that is part of the Regulation setting forth the CN.[10]

The average duty rate is around 5% depending on the country of export to the EU. The duty rates range from 1 - 3% for basic goods, such as raw materials, to up to 14% for goods like clothes and shoes or certain electronic products and around 20% for chocolate.

Duty Reduction Programs

The EU provides duty-free or reduced duty status primarily under three statutory programs or under the FTAs concluded by the EU.

Statutory Programs: Statutory tariff programs provide duty-free or duty-reduced entry either to certain imports from eligible countries in order to provide trade and economic benefits to those markets or on the basis of the interests of the EU's own industry. The list of eligible products and countries varies from program to program and can vary within each program over time. In order to qualify for duty-free or duty-reduced benefits under these programs, importers will need to verify that the products meet the requirements set forth in the programs. Key EU programs include:

- GSP: As mentioned above, the GSP allows a wide range of goods originating in developing countries to be customs cleared in the EU duty-free or at a reduced duty rate;
- duty suspensions[11] and tariff quotas:[12] [13] Duty suspensions and tariff quotas may be granted to enable EU enterprises to use raw materials, semi-finished goods or components without being required to pay the normal duties laid down in the Common Customs Tariff. Thus, their purpose is to stimulate the economic activity of EU industries, improving their competitive capacity, creating employment, modernising structures etc. Still, this can benefit exports from the country of production.

10 For the duty rates applicable in 2017, see the Regulation hyperlinked in footnote 2 above.

11 For duty suspensions currently applicable, see Council Regulation (EU) 2016/2390 of 19 December 2016 amending Regulation (EU) No 1387/2013 suspending the autonomous Common Customs Tariff duties on certain agricultural and industrial products at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.360.01.0014.01.ENG&toc=OJ:L:2016:360:TOC.

12 In the case of tariff quotas, the duties are suspended up to a maximum volume of imports of the products concerned. For tariff quotas currently applicable, see Council Regulation (EU) 2016/2389 of 19 December 2016 amending Regulation (EU) No 1388/2013 opening and providing for the management of autonomous tariff quotas of the Union for certain agricultural and industrial products at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.360.01.0001.01.ENG&toc=OJ:L:2016:360:TOC.

13 Whether a product is entitled to a duty suspension or a tariff quota is provided for in the TARIC database mentioned above.

Exporters to and importers into the EU should be aware of this possibility. Importers / user industries in the EU need to apply for duty suspensions / tariff quotas with the authorities in their EU Member State, but the decision will be taken at EU-wide level on a consensus basis; and,

- materials, components or semi-manufactured products can enter the EU duty-free for processing and the subsequent export of the product into which they were processed out of the EU. This may also open an interesting competitive avenue for exporters of materials, components or semi-manufactured goods and may allow them to compete more easily with their competitors in the EU. This is nevertheless subject to an authorisation by local customs authorities.

FTAs: The EU has entered into around 30 trade agreements offering some form of free trade and 5 agreements are finalized but have not yet entered into force. Originating goods, as defined under each FTA, enter the EU duty-free either immediately upon entry into force or have their duties phased out over a fixed transition period.

Note that there is some overlap between the countries benefiting from the GSP and countries with which there is some form of FTA. In those instances, the FTA will prevail, following a transition period, to the extent that it largely affords the same advantages as the GSP regime.

Detailed requirements for EU duty suspensions and FTAs, including eligible products and countries can be found in the EU's TARIC.[14]

Anti-dumping and Countervailing Duties

Certain products imported into the EU are subject to anti-dumping and/or countervailing duties, in addition to customs duties. These duties are applied to imported products that the EU government has determined are being sold in the EU at unfair prices or that have received foreign government subsidies to lower their prices.

By entering the 8-digit tariff heading of the product into the TARIC database[15] one can determine whether the product is subject to anti-dumping and/or countervailing duties and, if so, their level. The TARIC will

14 See the hyperlink in footnote 3 above.
15 See the hyperlink in footnote 3 above.

identify the specific product scope of these duties based on a 10-digit tariff heading also showing the level of the duties per exporter.[16]

Value added tax and excise duties

In addition to any import duties that may be due, the EU customs authorities also collect value added taxes (VAT) and excise duties upon importation. Under certain conditions, VAT paid by an importer can be offset or recovered. The VAT rates can vary significantly from EU Member State to Member State. There are standard rates which almost invariably are double digit rates exceeding 20%, but some Member States have reduced rates for certain categories of goods. In sum, the situation in each EU Member State must be assessed as regards the levying of import VAT.

Excise duties are charged at clearance typically on alcohol, tobacco and energy products. Other categories of goods might be subject to excise duties (such as coffee for example). Costs are typically passed on to the buyer. The excise duty rates may also vary by EU Member State and the situation in each Member State must be assessed to determine whether and what excise duties will be levied.

Country of Origin Marking

There is no general requirement in EU legislation to affix an origin label on a product. As regards textile products, there is, however, an EU Directive concerning marking and labelling of the composition of the fibres of the product and other information for the consumer on the quality of the product. The said Directive does not contain any provision to govern the identification of the country of origin. As regards food products, EU legislation exists concerning geographical indications and specific provisions also exist for meat (indications such as the country where the animal was born, raised, slaughtered and the country where the meat was cut are compulsory on the packaging). For cosmetics products as well, EU law requires the country of origin to be shown on the product label. It is therefore advisable to check the relevant sector-specific legislation. Furthermore, aside from these products for which there are EU-wide provisions, the EU Member State laws will have to be reviewed to determine whether an origin label must be affixed.

Regardless of whether there is a requirement to affix an origin label, exporters must ensure accuracy, as an inaccurate origin label risks violating consumer protection or fair competition provisions.

16 For further information on the EU's anti-dumping and anti-subsidy investigations, see the European Commission's website at http://trade.ec.europa.eu/tdi/.

As a rule-of-thumb the EU's non-preferential rules of origin should be applied when determining origin.

II. Product Regulatory Requirements

General

The importation of certain classes of merchandise may be prohibited or restricted to protect the economy and security of the EU, to safeguard consumer health and well-being and to preserve domestic plant and animal life.

Many of these prohibitions and restrictions on importations are subject to laws and regulations administered by authorities other than the customs authorities. These laws and regulations may, for example, prohibit entry; limit entry to certain ports; restrict routing, storage, or use; or, require treatment, labelling, or processing as a condition of release of the goods into the EU. In many instances goods can only be customs cleared by the customs authorities if these various additional requirements are met. Some of the most common categories of goods subject to additional regulatory requirements are described below. They are by no means exhaustive and aim at giving an illustration only.

Textiles and Apparel: There is no EU legislation specifically on the flammability of clothing. However, some EU Member States (e.g. the UK and Ireland) have national requirements on this. EU Member State requirements should be assessed to find out if there are any requirements or recommendations as regards flammability labelling. There is however an EU General Product Safety Directive which lays down general safety requirements that apply to all consumer products placed on the EU market. There is also a specific European standard (EN 14878:2007) for children's nightwear. Textile and fur apparel products are subject to labelling requirements.

Moreover, the EU has a Registration, Evaluation and Authorization of Chemicals Regulation (REACH Regulation) that requires all chemicals produced in or imported into the EU in volumes above 1 tonne per year to be registered. This includes all products, such as textiles and apparel, that may contain chemicals or chemical products.

CE Marking: To sell certain products in the 28 EU Member States, as well as in Norway, Liechtenstein, Switzerland, Turkey and Iceland, exporters are required to apply a so-called "CE marking" whenever their product is covered by specific product legislation. The CE mark certifies that a product has met EU health, safety and environmental requirements, which ensures

consumer and workplace safety. Once a manufacturer has earned a CE mark for its product, the CE mark may be affixed to the product, and then the product may be marketed throughout the EU without having to undergo further modifications in each Member State. There is no comprehensive list of the products that require a CE mark. Therefore, it is the manufacturer's responsibility to determine if a product requires a CE mark from various rules and regulations issued by the EU. Thus, for example, CE marking is required under the following EU directives: Safety of Toys, Medical Devices, Construction Products and Personal Protective Equipment.

Conformity Assessment: Several categories of products must demonstrate compliance with specified performance standards to ensure protection of health and safety, or compliance with conservation requirements. Many electronic products, among others, must comply with performance standards and are subject to documentation and labelling requirements.[17]

Other Requirements: The EU applies the procedures developed by more than 50 countries to exclude rough (uncut or unpolished) conflict diamonds from international trade while promoting legitimate trade in diamonds.[18]

The provisions of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) have been implemented in the EU through a set of Regulations known as the EU Wildlife Trade Regulations. CITES aims to ensure that international trade in specimens of wild animals and plants does not threaten their survival. It accords varying degrees of protection to more than 30 000 species of animals and plants. CITES works by making international trade in specimens of selected species subject to certain controls. These include a licensing system that requires the authorisation of the import and (re-)export of species covered by the Convention.[19]

In November 2016, an agreement was reached between the EU Member States and the European Parliament to adopt an EU regulation on conflict minerals, which aims to stop the financing of armed groups in developing countries through the trade of tin, tantalum, tungsten and gold. The regulation is set to ensure sustainable sourcing for more than 95% of all EU

17 See the European Commission's website at https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment_fr. See also the so-called "Blue Guide" on the application of EU product rules that deals with conformity assessment and CE marking at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2016:272:FULL&from=EN.

18 See the European Commission's website at http://ec.europa.eu/dgs/fpi/what-we-do/kimberley_process_en.htm. The governing rules can be found at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R2368:20130101:EN:PDF.

19 For details on the EU provisions and practice, see the European Commission's website at: http://ec.europa.eu/environment/cites/legislation_en.htm.

imports of tin, tantalum, tungsten and gold, which will be covered by due diligence provisions as of 1 January 2021.[20]

III. Introduction to EU Food Law

Scope of the EU food law

'Food' is any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in the drinking water legislation. 'Food' does not include feed, live animals unless they are prepared for placing on the market for human consumption, plants prior to harvesting, medicinal products, cosmetics, tobacco products, narcotic or psychotropic substances, residues and contaminants.

The EU food law (EU food law) consist of the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at EU or national level in the individual EU Member States. It covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals. It is adopted on the basis of scientific risk assessment under the supervision of the European Food Safety Authority (EFSA).

National rules supplementing the provision of the EU food law apply subject to the principle of mutual recognition. The principle of mutual recognition is defined in the EU case-law and implemented in the Mutual Recognition Regulation 764/2008 (the MR Regulation).[21] According to it, a Member State may not prohibit the sale on its territory of products which are lawfully marketed in another Member State, even though these products have been manufactured in accordance with rules different from those to which domestic products are subject, unless for overriding reasons of public interest and following the procedure set in the MR Regulation. Also, pursuant to the settled EU case-law, any national legislation which makes the marketing of products subject to a premarket authorization procedure restricts the free movement of goods. Nevertheless, such procedures could

20 See Regulation (EU) *2017/821* of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas (*Statements* by the Council and by the Commission).

21 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

be justified if (i) the national rules pursue a public interest objective recognized by EU law and comply with the principle of proportionality and (ii) the procedure itself can be regarded as "simplified".

Import and export of foods in the EU

The global reach of the EU food law is intended to be rather wide-ranging and to cover situations beyond the manufacturing and/or marketing of food within the EU. Under the Food Framework Regulation,[22] the "food business operator" can be any 'natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control' and the "food business" can be 'any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food'.

The EU food law applies to any foods intended to be placed on the market within the EU, including imported food. The Food Framework Regulation explicitly provides that imported foods must comply with the relevant requirements of EU food law or conditions recognized by the EU to be at least equivalent thereto or, where a specific agreement exists between the EU and the exporting country, with requirements contained therein.

The EU food law can also apply to foods manufactured in the EU for export or re-export. The general rule is that EU food intended for placing on the market of a third country must comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

Alternatively, foods which do not comply with the EU law can be exported or re-exported if (i) the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the EU and (ii) the safety of the exported food is not compromised and can be demonstrated.

Principles of EU food law

The EU food has two main primary objectives, *i.e.*, ensure a high level of protection of human health and consumer's interests. It strives to do so while taking into account the diversity in the supply of food, including traditional products in the EU Member States.

22 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

In order to achieve these objectives, the EU food law is built around the overall principles of (i) risk analysis, (ii) precaution, (iii) the protection of consumer's interests and (iv) transparent decision-making. The risk analysis comprises the risk assessment, risk management and risk communication. Depending on the nature of the measure to be used, food law and, in particular, measures relating to food safety must be underpinned by strong science.

The precautionary principle is a strategy to cope with possible risks where scientific understanding is yet incomplete and there are reasonable grounds for concern that an unacceptable level of risk to health exists. When faced with these specific circumstances, decision makers or risk managers may take measures or other actions based on the precautionary principle, while seeking more complete scientific and other data. Such measures have to comply with the principles of non-discrimination and proportionality and should be provisional until the time when more comprehensive information concerning the risk can be gathered and analysed.

Food safety

A food can only be placed on the market in the EU if its safety can be established. This means that the food should not be considered injurious and unfit for human consumption.

Safety of food must be assessed taking into account its normal condition of use by the consumer at each stage of production, processing and distribution and also to the food information provided to the consumer (*i.e.,* through labelling). Consideration must be given to the probable immediate, long-term and short-term effects and effects on subsequent generations, the probable cumulative toxic effects and the target population for which the food is intended (*i.e.,* health sensitive consumers).

Also, a food which is fit for human consumption should not be contaminated by extraneous matters or otherwise, or through purification, deterioration or decay.

Foods which comply with the EU food law or, in the absence of EU provision, with the national food law of the Member State where it is marketed, is deemed to be safe insofar as the aspects are covered by the applicable legislation. Nevertheless, the competentenforcement authorities can still take measures to restrict the placing of such foods on the market or withdraw them from the market if, despite the compliance, foods are actually unsafe.

The safety of the foods is the responsibility of all the business operators at all stages of production, processing and distribution within the business under their control. Operators should ensure the traceability of the food, feed, food-producing animals and any other substance intended to be, or expected to be incorporated into food and feed. They should implement systems allowing them to identify any person from whom they have been supplied and to whom their products have been supplied.

Labelling and nutrition

The EU implements the rights of consumers to get accurate and honest information about the content, composition and properties of the food products. Labelling helps consumers to make an informed choice while purchasing their foodstuffs.

Labelling: The EU food labelling rules[23] provides for the mandatory indication of the name and net quantity of the food, the name and address of the responsible food business operator, the date of minimum durability or the "use by" date of the food and, if needed, any special storage conditions and/or conditions/instruction of use. It must also provide the list of ingredients, emphasising those causing allergies or intolerances, and the nutrition declaration, including information about the energy value and the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

In some cases, the country of origin or place of provenance of the food could also be required (for instance, where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food). Finally, beverages containing more than 1,2 % by volume of alcohol must inform about the actual alcoholic strength by volume.

Nutrition and health claims: The EU also has specific rules on nutrition and health claims made on foods.[24] A claim is a message or representation, which is not mandatory under the EU or national laws, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics. By way of example, nutrition claims regulated under the EU food law are "low energy", "with no

23 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

24 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

added sugars", "sodium-free" or "salt-free", "source of fibre", "high protein", etc. can only be used subject to the conditions specified by the EU food law.

A health claim is a statement about a relationship between a food and the health. It can be about the beneficial effect of such food on the growth, development and functions of the body or about the reduction of a risk from a disease. For instance, foods containing α-linolenic acid (ALA) & linoleic acid (LA), essential fatty acids can claim that 'essential fatty acids are needed for normal growth and development of children', foods containing beta-glucans can claim that 'beta-glucans contribute to the maintenance of normal blood cholesterol levels', food containing calcium can claim that it contributes to 'the normal function of digestive enzymes', 'normal blood clotting', 'normal energy-yielding metabolism' and 'normal muscle function', etc.

Nutrition and health claims must be authorized and listed in the Nutrition and Health Claims Regulation 1924/2006. They must be specific, *i.e.,* made with respect to a specific nutrient or other substance which present, absent or reduced in the food at levels justifying the claimed effect. Claims should be scientifically substantiated and can only be permitted if the average consumer is expected to understand the beneficial effect they express.

Specific foods & food supplements: The EU also establishes specific rules regulating the composition, labelling and marketing of certain categories of foods, such as for instance (i) food supplements, (ii) fortified foods and (iii) food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (Food for Specific Groups).

Food business operators can place on the EU market food supplements, consumed in addition to the normal diet as concentrated sources of nutrients or other substances with a nutritional or physiological effect. Food supplements can be marketed in "dose" form, such as pills, tablets, capsules, liquids in measured doses, etc.[25] The Food Supplements Directive 2002/46/EC (FSD) establishes specific rules on the vitamins and minerals that are allowed for use in food, together with specific purity criteria. The EU harmonized rules are complemented by national provisions setting the minimum and maximum authorized levels for vitamins and minerals, conditions of use for other substances, plants and plant extracts, etc. (such rules exist in, amongst others, Belgium, Italy, Spain, etc.).

25 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

The FSD also provides for specific labelling rules that apply in addition to these set by the general EU food law. Food supplements must indicate the (i) name of the categories of nutrients or substances that characterize the product or an indication of the nature of these nutrients or substances, (ii) the portion of the product recommended for daily consumption and (iii) a warning not to exceed the stated recommended daily dose, etc.

Food fortification consist in the addition to foods of vitamins, minerals, amino acids, essential fatty acids, fibres, various plants and herbal extracts, etc. The EU has specific provisions on food fortification, including positive lists of vitamins, minerals and of certain other substances to foods set in Regulation 1925/2006.[26]

Finally, the EU has recently implemented new rules to strengthen the provisions on foods for vulnerable population groups and ensure their protection in the Food for Specific Groups Regulation 609/2013.[27] It establishes rules for the composition and placing on the market of (i) infant formula and follow-on formula, (ii) processed cereal-based food and baby food, (iii) food for special medical purposes and (iv) total diet replacement for weight control. It also establishes a single Union list of substances that can be added to these foods including minerals and vitamins. Further specific provisions exist per category of FSG.

Food improvement agents

Food additives,[28] food enzymes and food flavourings are also known as 'food improvement agents'. These substances are added to foods in order to achieve a given technological purpose during the processing or in the final food and are *in fine* ingested by the final consumer with this food. The EU has adopted extensive rules about the authorization, marketing and use of additive, enzymes and flavourings.

Additives: Food additives are substances not normally consumed as a food as such and not normally used as a characteristic ingredient of food, with or without a nutritional value. They are added to food for technological purposes in the manufacturing, processing, preparation, treatment, packaging, transportation or storage stages and become a component of such food. Additives can be used variety of reasons in foods production,

26 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

27 Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

28 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

i.e., as sweeteners, colours, preservatives, antioxidants, anti-caking agents, emulsifiers and packaging gases, etc.

Food additives can be used if their safety can be established, if they do not mislead the consumer and respond to a reasonable technological need that cannot be achieved by other economically and technologically practicable means. Sweeteners and colorants are subject to additional specific conditions for use. Sweeteners can only be used as sugar replacement and colorants should be used to restore the original colours of a food, make it visually more appealing or give colour to food otherwise colourless.

Additives must undergo an assessment by EFSA. They should be listed in the Food Additives Regulation 1333/2008 and can only be used subject to conditions, restrictions and use levels set therein. Additives which have been permitted before 20 January 2009 are currently subject a new risk assessment by EFSA.[29] An additive authorization can be granted for one or several food categories, *i.e.,* for use in dairy products, fats and oils, fruit and vegetables, cereals, confectionary, meat, fish, eggs, beverages, desserts, etc.

Food additives must also comply with the specifications, which should include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity.[30]

Additives must be distinguished from the processing aids, intended to perform a technological function only during the treatment or processing of the food. They may be present in the final food as unintentional but technically unavoidable residues of the substance or its derivatives provided that their safety can be established.

Processing aids are merely defined by the Food Additives Regulation 1333/2008 but excluded from its scope. Also, the EU does not establish further rules to regulate processing aids (some limited hygiene rules regulate processing aids used on foods of animal origin). National legislation on processing aids, including positive lists of authorized substances, exist in some EU Member States, for instance, in France.

Enzymes: Enzymes are products obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms: containing one or more enzymes capable of catalysing a specific biochemical reaction. They are

29 Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

30 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of foods.[31] Enzymes must be authorized by EFSA and listed in the Food Enzymes Regulation 1332/2008.

Flavourings: Flavourings are intended to impart or modify odour and/or taste. They consist of the following categories: flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors or other flavourings or mixtures there.

Flavourings can be used if their safety can be established and they do not mislead the consumer if they fall under one of the following categories: (i) food ingredients with flavouring properties, (ii) flavouring preparations obtained by food by appropriate physical, enzymatic or microbiological process either in the raw state of the material or after processing for human consumption by one of the traditional food preparation process listed in Annex II of the Food Flavourings Regulation 1334/2008,[32] (iii) thermal process flavouring obtained after heat treatment from food and (iv) flavour precursors obtained from food. Other flavourings must be authorized by EFSA and listed in the Food Flavourings Regulation 1334/2008.

Flavourings are also subject to specific labelling requirements. In particular, the Food Flavourings Regulation establishes specific requirements for the use of the term 'natural' in flavourings' labelling and sale description. For instance, the term 'natural' can only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source if the flavouring component has been obtained exclusively or by at least 95% by w/w from the source material referred to. Also, the term 'natural flavouring' maybe used if the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste.

Common authorization procedure: Finally, the EU has established a common authorization procedure for food additives, enzymes and flavourings, explicitly described in Regulation 1331/2008.[33] This procedure must be followed anytime when a substance must be added to or removed

31 Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.

32 Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC.

33 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

from a positive lists of authorized additives, enzymes or flavourings or when a modification of an existing listing is requested. The procedure for the updating of a positive list may be started either on the initiative of the Commission or following an application by an interested party. A substance can only be approved on the basis of a positive scientific opinion by the EFSA and a legislative measure adopted by the Commission.

Further guidance on the common authorization procedure is provided in the Implementing Regulation 234/2011,[34] which establishes rules for the content (administrative and scientific data needed for the assessment), drafting and presentation of an application for approval. It also provides for the different steps to be followed by the authorities in the evaluation of an application.

Food hygiene & HACCP system

The EU 'food hygiene' rules establish measures and conditions necessary to control the hazards and to ensure fitness of foods for human consumption. Food business operators must ensure compliance with these hygiene measures at all stages of the production, processing and distribution of foods under their control.[35]

To achieve that, food business operators should comply with (i) the microbiological criteria for certain microorganisms in foodstuffs (*i.e.*, bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites)[36] and (ii) the temperature control requirements for foodstuffs and the maintenance of the cold chain. They should implement procedures necessary to comply with the food hygiene rules, as well as an ongoing sampling and analysis of their production. Comprehensive hygiene rules for primary food production and other types of food production are established in the Annexes of the Food Hygiene Regulation 853/2004.

Food business operators must also implement and maintain permanent procedures based on the Hazard Analysis and Critical Control Points principles (the HACCP). The HACCP principles consist of the following:

- identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

34 Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

35 Regulation (EC) No 852/2004 of the European Parliament and of the council of 29 April 2004 on the hygiene of foodstuffs.

36 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

- identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- establishing and implementing effective monitoring procedures at critical control points;
- establishing corrective actions when monitoring indicates that a critical control point is not under control;
- establishing procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively; and,
- establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined above.

Food business operators should cooperate with the competent national authorities in the individual EU Member States and ensure that their establishments are approved by such authorities when an approval is required under the national law or pursuant to the EU rules on hygiene of foods of animal origin.[37] Operators must ensure that national authorities always have up-to-date information about their establishments and the activities carried out therein.

The EU has also established specific rules on hygiene of foods of animal origin, supplementing these set in the Food Hygiene Regulation 853/2004. Establishments handling food of animal origin are subject to specific stringent rules on approval, functioning and controls.

Novel foods

"Novel food" is defined as food that has not been consumed to a significant degree by humans in the EU prior to 15 May 1997, when the first Novel Food Regulation 258/97 came into force[38]. "Novel food" should also belong to one of four listed categories, including (i) foods and food ingredients with a new or intentionally modified primary molecular structure, (ii) foods and food ingredients consisting of or isolated from micro-organisms, fungi or

37 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

38 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

algae, (iii) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use and (iv) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

The assessment of the 'novelty' of a given food is performed on a case-by-case basis, taking into account all the characteristics of the food product and of the production process.[39]

The EU has recently adopted the new Novel Foods Regulation 2015/2283,[40] which will apply on 1 January 2018. Under the new Regulation, the definition of 'novel food' has been expanded to cover several new categories. For example, it is now clarified that engineered nanomaterials as well as some vitamins and minerals can be regarded as novel food. Also, the reference to 'production process not currently used' has been clarified to mean a 'production process not used for food production within the Union before 15 May 1997'. A new procedure also will be implemented to determine the 'novelty' of a given food by consulting the national authorities in the EU Member States and the Commission.

"Novel food" should be safe and should be authorized before it can placed on the market. Before the new legislation, 'novel food' had to be petitioned at national level in the individual EU Member States. Under the new rules, it will be subject to an EU centralized authorization procedure.

The new Novel Foods Regulation 2015/2283 facilitates the placing on the EU market of traditional foods from third countries, which qualifies as "novel" under the EU rules. If such foods have a history of safe use in at least one third of country for at least 25 years as a part of the customary diet of a significant number of people, they can undergo a simplified notification/ authorization procedure.

The EFSA has prepared guidance documents to facilitate the implementation of the new rules, *i.e.*, (i) a Guide on the application for

39 ECJ 15 January 2009 in Case C-383/07.

40 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.

authorization of a novel food[41] and (ii) a Guide on the notification and application for authorization of traditional foods from third countries.[42]

Food contact materials

Foods are often placed in contact with various materials and articles. By way of example, this can be any type of packaging materials, films and foils, boxes, beverage systems such coffee, cacao, milk capsules, but also sausage casings, tea bags and many others. Foods also regularly enter into contact with industrial equipment (conveyer bells) or home equipments (kitchen utensils, cooking equipment, different ovens, refrigerators, etc.). Such materials and articles transfer ingredients to the food by 'migration' and could be source of contamination.

The EU has established comprehensive food contact legislation, applicable to materials and articles, which in their finished state (i) are intended to be brought into contact with food, (ii) are already in contact with food and were intended for that purpose, (iii) 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.[43]

Food contact materials must not transfer their constituents to food in quantities, which could: (i) endanger human health, (ii) bring about an unacceptable change in the composition of the food or (ii) bring about a deterioration in the organoleptic characteristics of the food. The EU has thus established an overall limit on the migration of constituents into food and specific migration rules for some substances used in food contact materials.

Different food contact materials are subject to specific measures and composition requirements. Thus the EU has extensively regulated the manufacture and use of food contact plastics in the Plastics Regulation.[44] Such materials can only be manufactured using monomers and additives listed on the positive list of the Plastics Regulation and subject to assessment by the EFSA and authorization by the European Commission. Also, authorized monomers and additives may be subject to specific migration limits, which is the maximum permitted amount of a substance released from a material or article into food.

41 Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

42 Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283.

43 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.

44 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

Many other food contact materials, such as metals, paper, rubber, silicones, inks, coatings, etc., but not (yet) regulated at the EU level and are (still) subject to national legislation in various Member States (*i.e.,* France, the Netherlands, Belgium, Spain, Italy, etc.) and the principle of mutual recognition.

Finally, the EU has also adopted specific "good manufacturing practices", which ensure that food contact materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics.[45]

IV. Introduction to EU Cosmetics Law

Scope of the EU cosmetics law

Cosmetic products marketed in the EU are subject to the harmonized rules set in the EU Cosmetics Regulation 1223/2009 (Cosmetics Regulation).[46] The Cosmetics Regulation is directly applicable as such into the national law of the EU Member States and does not require any national transposition.

A "cosmetic product" is any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

The Cosmetics Regulation provides examples of cosmetic product such hair products, skin, lips, face, nail products. 'Products applied on mucous membranes' are cosmetics intended to be applied on the mucous membranes (i) of the oral cavity, (ii) on the rim of the eyes or (iii) of the external genital organs. The Regulation also distinguishes between the "rinse-off products", intended to be removed after application on the skin,

45 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.

46 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).

the hair or the mucous membranes, and the "leave-on product" intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

The primary purpose of cosmetics cannot be to destroy, deter, render-harmless, prevent the action of or exert a controlling effect on any harmful organism by chemical or biological means. Such products would fall rather fall within the scope of the EU biocides legislation[47] and be subject to the authorization procedures set forth therein. Examples include products making claim to control public health through the control of infectious organisms, such as *"disinfecting"*, which would go beyond the general knowledge of personal hygiene as a contribution to public health, considering the reasonable expectations of the average consumer relating to biocidal activity, and can include antibacterial hand gels, and antibacterial bar or liquid soaps with an additional public health claim.[48]

The purpose of cosmetics should neither be to restore, correct or modify the physiological functions of human beings by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, in which case they would be medicinal products, subject the comprehensive authorization procedures set in the Medicinal Products Directive.[49] The European Court of Justice (the ECJ) has also ruled that 'a product expressly indicated or recommended as having therapeutic or prophylactic properties has to be regarded as a medicinal product 'by virtue of its presentation' even if it has no known therapeutic effect",[50] and that the "averagely well-informed consumer" is to be considered as the addressee of the presentation.[51]

The EU does not have a harmonized definition of "disease" or a database of diseases. Therefore, the assessment of whether a product is a cosmetic product has to be made on a case-by-case basis, taking into account all

47 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
48 Note for Guidance CA-Jul13-Doc.5.1.h 'Borderline between the legislation for cosmetics and biocides'.
49 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
50 Judgment of the Court of 28 October 1992 in case C-219/91 "Wilhelmus Ter Voort", par.18.
51 Judgment of the Count of 30 November 1983 in case C-227/82 "Van Bennekom", par.18.

characteristics of each product. Some indications are provided in ECJ case law as well as in Q&A tools by the European Commission.[52]

The Cosmetics Responsible Person

The Cosmetics Regulation establishes the main rules and requirements which regulate the manufacturing and marketing of cosmetics in the EU. It is supplemented by specific rules regulating the safety assessment, labelling and the cosmetic claims. Importantly, compliance with all these requirements is specifically assigned to the so called Responsible Person (RP), who can be the cosmetics manufacturer, established in the EU, the EU importer or any other person established in the EU and designated in a written mandate, accepted in writing. Accordingly, foreign manufacturers selling cosmetics product in the EU without being the importer must designate a RP in the EU.

Substances used in cosmetics

The EU does not establish a general authorization procedure for substances and ingredients used in cosmetics, *i.e.,* there is no one EU positive list of authorized cosmetic substances ingredients.

Instead, the Cosmetics Regulation establishes a negative list of prohibited substances (in Annex II) and a list of restricted substances that can only be used in cosmetics subject to conditions and limitations (in Annex III). The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice is however accepted, provided that such presence does not compromise the safety of cosmetics.

The Cosmetics Regulation also prohibits the use in cosmetics of substances, which have been subject to an EU harmonized classification as carcinogenic, mutagenic or toxic for reproduction (CMR) substances of category 1A or 1B and are listed as such in Part 3 of Annex VI to Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation).[53] By way of exemption, such substances can be used only if they meet four cumulative conditions, *i.e.,* (i) they comply with the Food Framework Regulation 178/2002,[54] (ii) there are no suitable

52 Manual on the scope of application of the Cosmetics Regulation (EC) no 1223/2009 (art. 2(1)(a)) version 1.0 (November 2013).

53 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

54 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

alternative substances available, as documented in an analysis of alternatives, (iii) the application is made for a particular use of the product category with a known exposure and (iv) they have been evaluated and found safe by the Scientific Committee on Consumer Safety (the SCCS) for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources and the vulnerable population groups. Also, CMR substances of category 2 are also prohibited, unless they have been evaluated by the SCCS and found safe for use in cosmetic products.

Unlike other ingredients, the EU establishes positive lists of colorants, preservatives and UV-filters which can only be used in cosmetics if evaluated by the SCCS, approved by the European Commission (comitology procedure) and listed, respectively in Annex IV, V and VI of the Cosmetics Regulation.

Finally, the European Commission maintains the so-called CosIng database,[55] which provides information on cosmetic substances and ingredients used by the industry and/or listed in the Cosmetics Regulation, addressed in SCCS scientific opinions and/or the Inventory of Cosmetic Ingredients.[56] This database is an informative tool, which is neither mandatory nor exhaustive.

Safety of cosmetic products

Cosmetics can only be made available on the EU market if they are safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of their presentation, labelling, instructions for use and disposal, as well as any other indication or information provided by the RP.

Safety of cosmetics intended for the EU market should be established on the basis of a comprehensive Safety Assessment (the SA), which must be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognized as equivalent by a Member State. The SA must take into account the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation. It must be conducted using an appropriate weight-of-evidence approach for reviewing data from all existing sources.

55 Cosmetic ingredient database.

56 Commission Decision 96/335/EC of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products.

The RP must ensure that a Product Safety Report (PSR) is established in accordance with the Annex I to the Cosmetic Regulation, as implemented in the Commission Decision 2013/674/EU.[57] Such PSR must be kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

The PSR is divided in two parts, *i.e.,* Part A must provide "Cosmetic product safety information", including information on (i) quantitative and qualitative composition of the cosmetic product, (ii) physical/chemical characteristics and stability of the cosmetic product, (iii) microbiological quality, (iv) impurities, traces, information about the packaging material, (v) normal and reasonably foreseeable use, (vi) exposure to the cosmetic product, (vii) exposure to the substances, (viii) toxicological profile of the substances, (ix) undesirable effects and serious undesirable effects and (x) information on the cosmetic product.

Part B of the PSR comprise the SA and must provide (i) the SA conclusion and a general statement on the safety of the cosmetic product, (ii) if relevant, a statement on the need to label any particular warnings and instructions of use, (iii) an explanation of the scientific reasoning based on the information provided in Part A and leading to the assessment conclusion and the statement on warnings and instructions of use and (iv) the assessor's credentials and proof of qualification. Part B should provide *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Finally, the manufacture of cosmetic products must comply with Good Manufacturing Practice (GMP). Further rules on compliance with GMP in the production, control, storage and shipment of cosmetic products are established in standards, which can be used on a voluntary basis.[58]

Animal testing ban

The Cosmetics Regulation prohibits companies to (i) perform animal testing of finished cosmetic products and/or cosmetic ingredients on the EU territory in order to meet the requirements of the Cosmetics Regulation and (ii) place on the EU market finished cosmetic products and/or cosmetic ingredients which have been tested on animals in order to meet the requirements of the Cosmetics Regulation.

57 Commission Implementing Decision 2013/674/EU of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

58 ISO 22716:2007 Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices.

Since the animal testing ban was fully implemented in 2013, the meaning of 'in order to meet the requirements of the Cosmetics Regulation', and hence the practical implication of animal testing ban, have been subject to different interpretations. In particular, it was discussed:

- whether the ban is restricted to vertebrate animal testing conducted for the protection of human health (human health end-points), as opposed to the protection of the environment, which is not part of the scope of the Cosmetics Regulation; and,
- whether and to what extend vertebrate animal testing conducted for purposes of ensuring compliance with other EU legislation (i.e., REACH, food legislation, medicinal product) or with non-EU legislation (i.e., non-EU cosmetics or non-cosmetics legislation) can be carried out and whether the tested ingredients can then be used in the EU (as they were not tested 'in order to meet the requirements of the Cosmetics Regulation') or are subject to the ban.

The ECJ has recently clarified some aspects of the above discussion. While the ECJ did not prohibit the placing on the market in the EU of cosmetic ingredients tested on animals after the implementation of the ban, it ruled that companies cannot rely on results from animal tests conducted outside the EU to support the safety of cosmetic products placed on the market within the Union.[59] Specifically, the ECJ said the Cosmetics Regulation prohibits:

> the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.

However, it is still unclear whether data from tests performed for non-cosmetic purposes (i.e., data generated for REACH[60] or to comply with the rules on workers exposure) can still be relied upon in the safety assessment of cosmetics marketed in the EU. Prior to the ECJ ruling, the Commission considered that the results from tests conducted for mixed applications (*i.e.*,

59 Judgment of the Court of of 21 September 2016 in Case C-592/14, par.46.

60 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

cosmetics and non-cosmetics) could be used for the safety assessment of cosmetics placed on the EU market.[61] The validity of such interpretation is vigorously questioned by the civil society and, specifically, by animals' protections organizations.

Testing of cosmetic ingredients

The SCCS has compiled a "Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation by the SCCS" (Notes of Guidance).[62] The emphasis is on cosmetic ingredients, although some guidance is also given for the safety assessment of finished products. It is designed to provide guidance to public authorities and to the cosmetic industry in order to improve harmonized compliance with the current cosmetic EU legislation.

The Notes of Guidance should not be seen as a checklist but have been compiled to provide assistance in the complex process of the testing and safety assessment of cosmetic ingredients in the EU. The document is regularly revised and updated in order to incorporate the progress of scientific knowledge in general, and the experience gained in particular, in the field of testing and safety evaluation of cosmetic ingredients.

Product Information File

When a cosmetic product is placed on the EU market, the RP must keep a Product Information File (PIF) readily accessible in electronic or other format at his address indicated on the label of the product. The PIF must be regularly updated and kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

The PIF must contain the following information:

- a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
- the cosmetic PSR;
- a description of the method of manufacturing and a statement on compliance with GMP;
- where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product; and,

61 Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics COM(2013) 135 final.

62 The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 9th revision, SCCS/1564/15, Revised version of 25 April 2016.

- data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

The information contained in the PIF must be available in a language which can be easily understood by the competent authorities of each of the Member States, where the product is placed on the market.

Notification of cosmetic products

Prior to placing a cosmetics on the EU market, the RP must submit an electronic notification to the Commission. By way of exemption, cosmetics containing nanomaterials must be notified by the RP six months prior to being placed on the market, except where they have already been placed on the market by the same RP before the entry into application of the Cosmetics Regulation in 2013.

The notification should be made via the Cosmetic Product Notification Portal (the CPNP),[63] a free of charge online notification system created for the implementation of Cosmetics Regulation. When a product has been notified in the CPNP, there is no need for any further notification at national level within the EU.

The notification must contain the following information:

- the category of cosmetic product and its name or names, enabling its specific identification;
- the name and address of the responsible person where the product information file is made readily accessible;
- the country of origin in the case of import;
- the Member State in which the cosmetic product is to be placed on the market;
- the contact details of a physical person to contact in the case of necessity;
- the presence of substances in the form of nanomaterials and their identification including the chemical name (IUPAC) and other descriptors as specified in the Cosmetics Regulation;

63 Cosmetic Product Notification Portal.

- the reasonably foreseeable exposure conditions;
- the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as CMR of category 1A or 1B in Part 3 of Annex VI to CLP Regulation; and,
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The notification should also contain examples of the original labelling and, where reasonably legible, a photograph of the corresponding packaging. It should also provide additional specific information about nanomaterials.

Finally, distributors making available in a Member State a cosmetic product already placed on the market in another Member State on their own initiative, also have some more limited notification obligations.

The Commission makes the notified information available by electronic means to all competent authorities in the EU Member States, as well as to poison centres or similar bodies, where such centres or bodies have been established by Member States.

Labelling of cosmetics

Cosmetics can only be marketed in the EU if their container and packaging bear in indelible, easily legible and visible lettering a certain number of mandatory particulars, including:

- the name or registered name and the address of the RP (possible abbreviated);
- the country of origin for imported cosmetic products;
- the nominal content at the time of packaging;
- for cosmetics with a minimum durability below 30 months: the date of minimum durability, referred to by the relevant symbol or the words ‘best used before the end of’;
- for cosmetics with a minimum durability above 30 months the ‘period of time after opening’, referred to by the relevant symbol followed by the period (in months and/or years);
- particular precautions to be observed in use, and at least those listed in Annexes III to VI of the Cosmetics Regulation and any special precautionary information on cosmetic products for professional use;

- the batch number of manufacture or the reference for identifying the cosmetic product;
- the function of the cosmetic product, unless it is clear from its presentation; and,
- the list of ingredients, preceded by the term "ingredients".

For the purpose of labelling, an ingredient is any substance or mixture intentionally used in the cosmetic product during the process of manufacturing, excluding (i) impurities in the raw materials used and (ii) subsidiary technical materials used in the mixture but not present in the final product. Perfume and aromatic compositions and their raw materials should be referred to by the terms "parfum" or "aroma". All ingredients present in nanoform should be clearly indicated as such the list of ingredients.

The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %. Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients.

The Cosmetics Regulation provides that where for practical reasons all the above information cannot be provided (*i.e.,* very small packaging), it can be abbreviated or provided on an enclosed or attached tag, tape or card or in an enclosed leaflet, in immediate proximity to the container in which the cosmetic product is exposed for sale. The relevant symbol must be used to indicate reference to enclosed or attached information (see symbols in the annex).

Cosmetics claims

The Cosmetics Regulation provides that in "the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have".

The Cosmetic Claims Regulation[64] establishes further comprehensive rules on cosmetic claims in the form of texts, names, trademarks, pictures and figurative or other signs that convey explicitly or implicitly product

64 Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

characteristics or functions in the labelling, the making available on the market and advertising of cosmetic products.

In particular, cosmetic claims must satisfy six common criteria, *i.e.,* (i) legal compliance, (ii) truthfulness, (iii) evidential support, (iv) honesty, (v) fairness and (vi) informed decision-making. By way of example, the "legal compliance" rule prohibits the use of claims that indicate that the product has been authorized or approved by a competent authority within the Union and/or which convey the idea that a product has a specific benefit when this benefit is in mere compliance with minimum legal requirements shall not be allowed. The "truthfulness" rule requires that when a cosmetic product claims that it contains a specific ingredient, this ingredient should be deliberately present in it.

Cosmetic claims should be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including appropriate expert assessments. The level of evidence or substantiation must be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem.

They should be clear and understandable to the average end user and take into account the capacity of the target audience.

The EU Commission has developed specific Guidance document for the implementation of each of the above common criteria, also providing specific examples of acceptable or prohibited claims.[65]

Finally, some cosmetic claims can be subject to specific EU rules, such for instance efficacy claims made on sunscreen products.[66]

Industry Guidance documents

The EU legislation on cosmetics is often supplemented by industry guidance documents, *i.e.,* by Cosmetics Europe, formerly Colipa, the International Fragrance Association (IFRA). Such guidance documents are of course not legally binding for operators but can be a helpful tool in assessing obligations pursuant to the EU legislation on cosmetics.

65 Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products; Ref. Ares (2015) 5892153 - 16/12/2015.

66 Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (notified under document number C(2006) 4089).

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