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Essential Oils: Market and Legislation

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Additional information is available at the end of the chapter

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Abstract

This chapter provides an overview of the market for essential oils and describes its fundamental regulation in the European Union (EU). Both processes and trends in essential oils production, trade, and consumption are analysed. Growth of the market stems from consumer interest in 'naturals' associated with health. The market is also attractive to subsistence farmers of developing countries as the raw materials (plants and plant parts), for essential oils are generally obtained from small farms. In the EU, product categories operate under specific regulations to enhance product quality and to maintain market homogeneity and consumer protection. This chapter focuses on EU legislation of general interest to the essential oils industry and regulations inherent to flavourings for food, cosmetics, and additives for animal nutrition.

Keywords: essential oil, regulation, production, trade, consumption, chemical, labelling, food, cosmetics, flavouring, aroma, additive, animal nutrition, EU

1. Introduction

This chapter provides an overview of the essential oils market and illustrates the main regulatory aspects for their primary uses in the European Union (EU). According to the European Pharmacopoeia [1], an essential oil is an 'odorous product, usually of complex composition, obtained from a botanically defined plant raw material by steam distillation, dry distillation, or a suitable mechanical process without heating'. The norm of the International Standard Organisation (ISO) ISO 9235:2013/Cor 1:2014 defines 'Aromatic raw materials—Vocabulary' [2] as a 'product obtained from a natural raw material of plant origin, by stem distillation, hydro-distillation, dry distillation, mechanical process...'. Both sources indicate that essential oils are distilled products, as opposed to extracts [3], liquid products obtained from plant parts (leaves, stems, bark, seeds, fruits, roots, and plant exudates), or, at times, may be produced by other

processes, including solvent extraction. They are generally of complex composition and contain alcohols, aldehydes, ketones, phenols, esters, ethers, and terpenes in varying proportions. The oils are also called 'volatile or ethereal oils' for several reasons: they evaporate when exposed to heat in contrast to fixed oils; they are odorous and volatile compounds found only in 10% of the plant kingdom; and they are stored by plants in special brittle secretory structures (glands, secretory hairs, secretory ducts, secretory cavities, or resin ducts) [4–11]. Distillation is the most common method to isolate essential oils, but other processes—including *enfleurage* (extraction using fat), maceration, solvent extraction, and mechanical pressing—are used for specific products. The most suitable extraction method depends mainly on the raw material from which the oil is being extracted, for example, expression by mechanical or cold press is commonly used to extract essential oils from citrus peels. Younger plants produce more essential oil than older ones, but old plants are richer in more resinous and darker oils due to the continual evaporation of lighter oil fractions. The function of essential oil in a plant is not well understood. Flower odours are thought to aid natural selection by acting as attractants for particular insects, while leaf-, wood-, and root-derived oils may protect against plant parasites or depredations by animals. Oleo-resinous exudations that appear with tree trunk injury prevent sap loss and create a protective sealant against parasites and disease organisms. Few essential oils are involved in plant metabolism; in fact, some investigators maintain that many of these materials are simply waste products of plant biosynthesis [12]. Of the estimated 3,000 essential oils known, approximately 150 are of commercial importance currently and traded on the world markets [13–18]. While they are called oils, they should not be confused with 'fixed' or fatty oils that actually are lipid-based and may or may not be volatile. Indeed, essential oils differ chemically and physically from fixed oils. The essential oils produced predominantly for industrial purposes are those from orange, corn mint, eucalyptus, citronella, peppermint, and lemon [18]. The oils commonly used for domestic purposes include lavender, chamomile, peppermint, tea tree oil, eucalyptus, geranium, jasmine, rose, lemon, orange, rosemary, frankincense, and sandalwood. Essential oils constitute a major group of agro-based industrial products and have applications in various industries, such as food products, beverages, perfumes, pharmaceuticals, and cosmetics [19–25]. While aromatherapy represents a recent and growth niche for the market, their use is well established in the food, flavouring, and fragrance industries. The soft drink industry is the largest user of essential oils, especially those originating from *Citrus* oil. In fact, no 'cola' is produced without lemon or lime essential oils. Other prime users include alcoholic beverage makers, manufacturers of sweet, dairy, confectionary, and dessert products, as well as fast and processed foods, all in the food sector. Essential oils also have applications in other industries: pharmaceuticals, cosmetics, supplements, herbals, and feeds. This chapter describes EU legislation for essential oils used in flavourings, cosmetics, and additives in animal nutrition. From ancient times to today, essential oils have been recognised for their powerful natural plant products and medicinal value. They have been used as perfumes and food and beverage flavourings, even to heal the body and the mind for thousands of years [26–29]. The natural chemicals of essential oils operate via multiple modes of action as follows: antifeedant and repellent activities, moulting and respiration inhibition, growth and fecundity reduction, and cuticle disruption. They can function as contact, fumigant, repellent, antifeedant, and

oviposition inhibition toxicants. Furthermore, essential oils have been widely used as anti-parasites, bactericides, fungicides, antivirals, and insecticides.

2. Markets for essential oils

The following section presents statistical data on essential oil production, trade, and consumption. Essential oils are industrial products. Available data, generally, are not specific to essential oils but are part of aggregated product data.

2.1. Production of essential oils

Estimation of essential oil world production and trade is fraught with difficulties [30]. In many countries, neither domestic production nor export statistics are recorded for some of the highest volume oils, while the rest are often buried in codes encompassing a range of products. Therefore, global production publications must be treated with caution and scepticism, as the information generally ignores domestic consumption and is frequently based on data from only a few countries. In reality, a wide range of countries from every continent are involved as producers. Worldwide essential oils production was estimated in 2017 (**Figure 1**) as more than 150,000 tonnes valued at about \$6B USD [31], which represents a tripling in volume since 1990 (45,000 tonnes), 50% of which has occurred since 2007. According to several economic analyses, growth will continue and by the 2020s is expected to reach 370,000 tonnes annually and be valued at more than \$10B USD (current dollars) [32, 33]. Essential oils are generally of

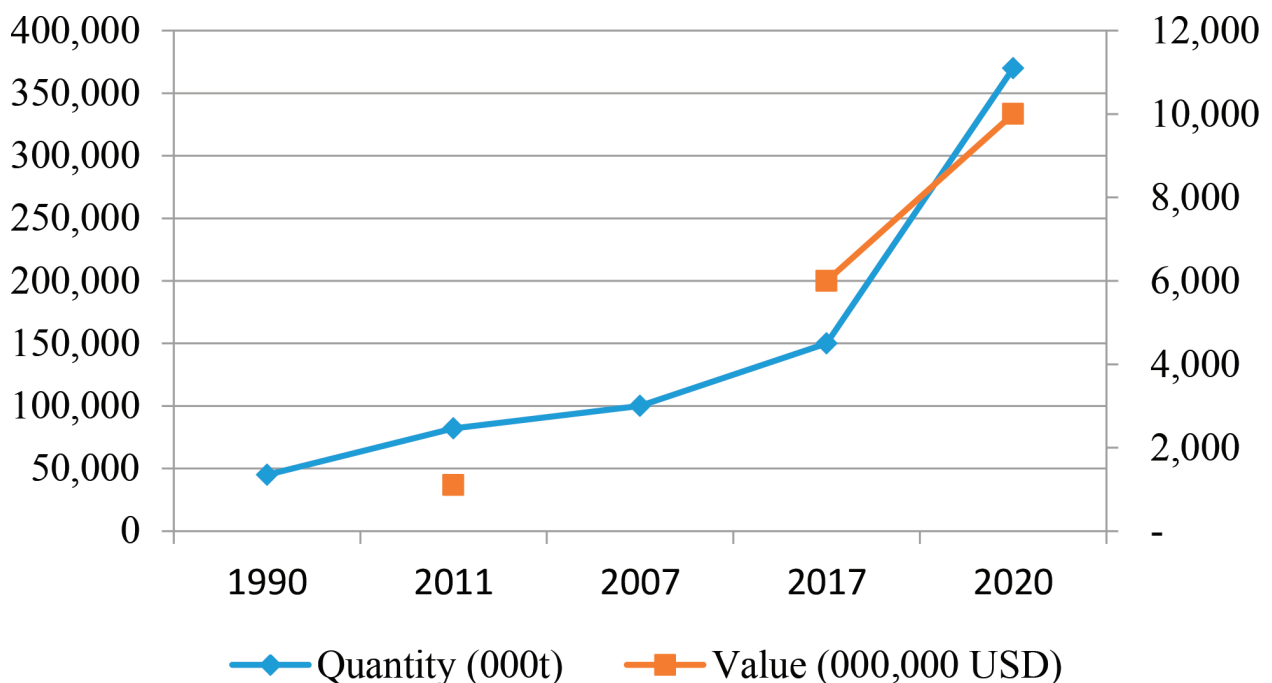


Figure 1. World production of essential oils (000 t; 000,000 USD). Source: EFEO, ISMEA.

complex composition and contain alcohols, aldehydes, ketones, phenols, esters, ethers, and terpenes in varying proportions. The major producers of essential oils across the world are China and India, followed by Indonesia, Sri Lanka, and Vietnam. Major essential oil-producing countries in Africa include Morocco, Tunisia, Egypt, and Algeria; the Ivory Coast, South Africa, Ghana, Kenya, Tanzania, Uganda, and Ethiopia play minor roles [34]. The North American continent is also a major essential oil producer. The United States (US), Canada, and Mexico all possess major natural aromatic plant materials, while Argentina, Paraguay, Uruguay, Guatemala, and the island of Haiti also make sizeable contributions to sector productions. Apart from the above mentioned major oil-producing countries, there are many others of less importance, such as France, Germany, Taiwan, Japan, Jamaica, and the Philippines. Many producers also come from developing country low-cost peasant-type operations and economies (65% of world production). The examples are numerous: orange derivatives produced in Brazil and China, corn mint in India and China, lemon in Argentina and Spain, Eucalyptus in China and India, peppermint in the US and India, citronella in China and Indonesia, saffras in China, lime in Mexico, lavandin in France and Spain, and Patchouli in Indonesia and China. Key market drivers include rising consumer preference for natural products, growing popularity of relaxation therapies (spa, aromatherapy, flavourings, and fragrances), increasing disposable income from higher living standards, and growing awareness of chemical substance side effects. The excellent antibacterial and antiseptic properties and aromatic flavourings of essential oils have also boosted their overall popularity. Also of help to the market in general is the expectation that raw material prices, on which the essential oils market is highly dependent, are expected to be stable in the near future. Data from the European Federation of Essential Oils (E.F.E.O.) [3] indicates that world essential oils production covers about 600,000 ha of the 1.6 billion ha in agricultural production. Approximately 1 million farms are producers in the sector, which represents 0.06% of total farms in the world (1,600 million). The top three essential oil crops (orange, mint, and lemon), about 100,000 tonnes, represent more than two-thirds of the total essential oil crop production. A number of essential oils are produced on small farms or collected from forests: Patchouli, Litsea, Citronella, *Eucalyptus globulus*, Clove leaf (production range: 1,000–10,000 tonnes), as well as Vetiver, Geranium, Ylang Ylang, Nutmeg, Lavender (production range: 50–400 tonnes). Small farmers continue to dominate essential oils production and therefore make an important contribution to the local incomes of relatively poor rural populations in developing countries. Aside from the socio-economic importance to the producing communities, these crops play important environmental roles. Many are short- or long-term perennial crops that provide stable environments; cultivation of many relies on long-established and traditional varieties that act to balance the surrounding flora. In addition, wild crafted crops support the maintenance of natural vegetation and its flora and fauna complexes. The European market for essential oils continues to grow at a healthy rate, as demonstrated by the development of leading flavouring manufacturers. Most are based in Europe, where they produce flavourings for food and beverage manufacturers, both inside and outside Europe. According to Eurostat data, over the last decade, the EU has increased production of essential oils by 41% and more than doubled its value (**Figure 2**) [35]. As for the value trend, it is always rising, except for a 2009 drop. On the other hand, production volume has decreased since 2011, although as of 2016, a counter-trend has emerged and shown a slight rise. In fact, during 2006–2016, Germany increased its production more than 50%; similar trends occurred in Spain, Greece, and the UK. In 2016, total EU essential oils production was valued at €902 M and yielded about 41 million kg.

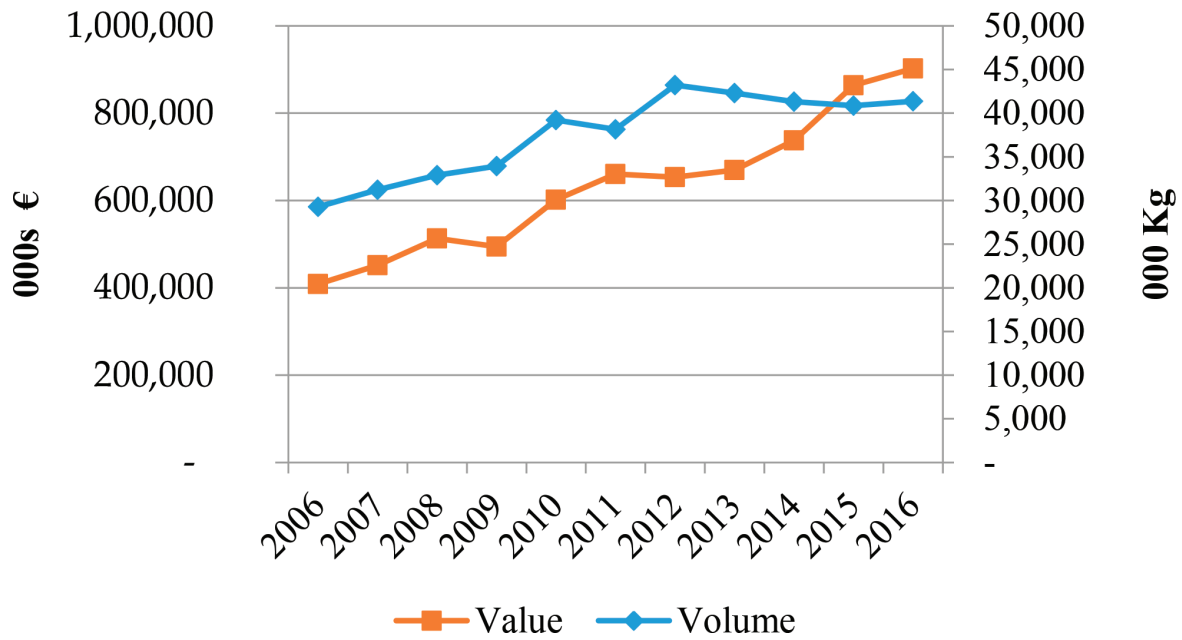


Figure 2. Essential oils production in the EU-28 (2006–2016; 000s €; 000 kg). Source: Eurostat.

Among EU member states overall, Germany consistently ranks as the top volume producer and in 2016 represented 46% of the essential oils produced (about 19 million kg) and 23% of their value. During this same decade, France made the largest gains in value by growing its sales by 90%. Over the same decade, Germany, Spain, and the US recorded even larger increases. In 2016, France was the top value producer and accounted for 34% of total EU-28 value; the country ranked second in quantity at 7 million kg. Other important European producers include Spain, the UK, and Italy (Table 1). For France, Spain and the UK, resinoides (€ 72M) deliver sizeable portions of both value and quantity production of these states, and concentrates do the same for France, Bulgaria, the UK, and Portugal.

2.2. World trade of essential oils

In 2016, the world exported \$4.38B USD in essential oils and import is \$4.54B USD (Figure 3) [36]. In rank order, these were the top exporters: the US (\$47B USD), Germany (\$28B USD), the UK (\$26B USD), and France (\$22B USD) [37], and the top importers were France (\$65B USD), the US (\$47B USD), Germany (\$41B USD), and Ireland (\$35B USD). As a group, the EU is the world’s biggest importer of essential oils, with France, Germany, and the UK being the major countries. Based on geography, Europe dominates the essential oils market, accounting for about 40% of world exports in 2016. The region is expected to maintain its pre-eminence throughout the analysis period due to growing demand for natural cosmetics, rising awareness, and increasing adoption of innovative essential oils in various sectors.

2.2.1. European imports

Over the five-year period from 2012–2016, the EU essential oils import values grew considerably to a peak (Figure 4), while import volumes remained relatively constant, which reflects a rise in unit price. Imports reached nearly 60,000 tonnes in 2016 to a value of €1.2B. Developing

Country	Essential oils		Resinoids		Concentrates of essential oils in fats... aqueous distillates, etc.	
	Value (000s €)	Volume (Kg)	Value (000s €)	Volume (Kg)	Value (000s €)	Volume (Kg)
Belgium	:C	:C	-	-	:C	:C
Bulgaria	34.413	158	:C	:C	7.412	1.022
Czech Republic	2.378	54	-	-	:C	:C
Denmark	523	18	-	-	1.052	165
Germany	206.437	18.907	:C	:C	:C	1.718
Estonia	-	-	-	-	-	-
Ireland	:C	:C	-	-	-	-
Greece	1.201	216	-	-	-	-
Spain	115.170	5.760	16.022	4.767	3.560	758
France	340.602	7.005	27.685	634	14.932	2.484
Italy	53.662	3.638	5.968	96	1.109	102
Cyprus	-	-	-	-	-	-
Latvia	-	-	-	-	-	-
Lithuania	2	0	-	-	13	34
Luxembourg	-	-	-	-	-	-
Hungary	2.961	88	-	-	-	-
Malta	-	-	-	-	-	-
The Netherlands	:C	:C	:C	:C	:C	:C
Austria	26.027	594	-	-	:C	:C
Poland	3.699	:C	:C	:C	:C	:C
Portugal	502	56	-	-	4.256	344
Romania	:C	:C	-	-	-	-
Slovenia	:C	:C	-	-	-	-
Slovakia	:C	:C	-	-	:C	:C
Finland	-	-	-	-	-	-
Sweden	-	-	-	-	-	-
The United Kingdom	98.815	3.620	10.962	CE	4.809	:C
Croatia	1.836	1	-	-	282	22
EU28	902.439	41.359	72.410	6.034	80.000	7.525

:C The data is confidential.

Table 1. EU-28 production of essential oils, resinoides and concentrades of essential oils (2016; 000 Kg; 000s€). Source: Eurostat.

countries played a relatively large and growing role by supplying Europe with 45% of its total imports. Imports from such countries represented a 2% increase as opposed to decreases of 14% and 11% from other European and non-developing countries, respectively. Of the trend in

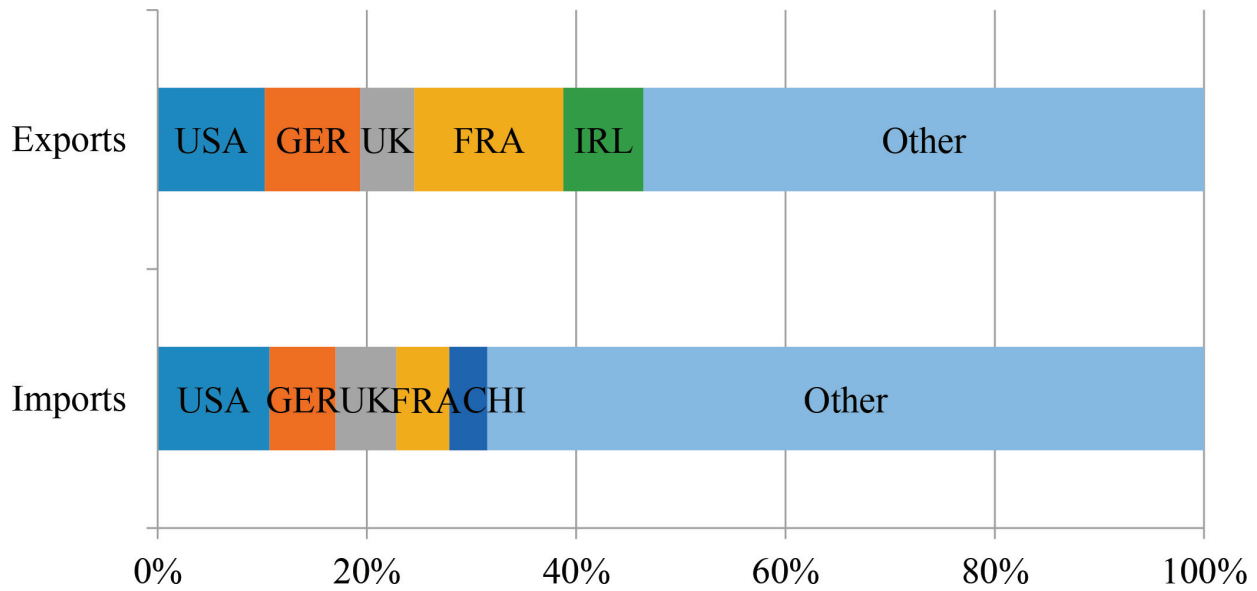


Figure 3. Import and export of essential oils in the world (2016, % value). Source: COMTRADE.

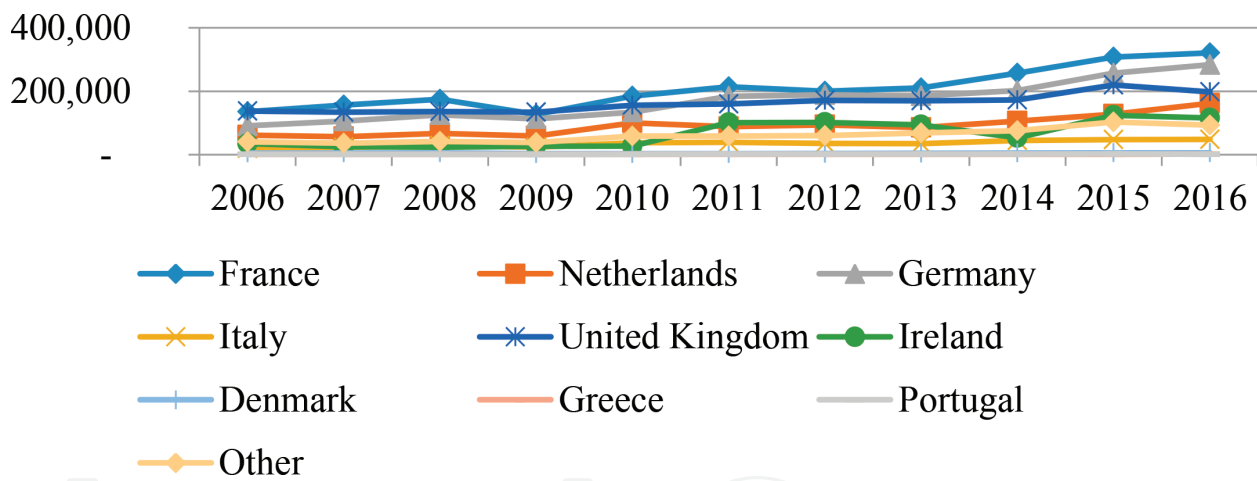


Figure 4. Import of essential oils in the EU-28 (2006-2016; 000s €). Source: Eurostat.

the EU-28, major importers (France, Germany, and the UK) all trended lower in 2012–2016, with the UK falling a remarkable 10%. The same negative trend was exhibited by Spain, Portugal, Denmark, and Ireland. The most recent year of records indicate that Greece and the Netherlands increased their import of essential oils by 27% and 35%, respectively. As mentioned earlier, for the decade ending in 2016, Germany, the Netherlands, the UK, and France were all major volume importers in Europe (Figure 5). Top ranked by volume, Germany is both a major and a stable importer of orange, peppermint, and other mint oils commonly used in the food industry. As was true for Europe generally, the value of orange oil imports by Germany grew substantially (14% annually), according to COMTRADE data. The increase resulted from price rises of orange oil after a drought in Brazil, which is the world’s principal

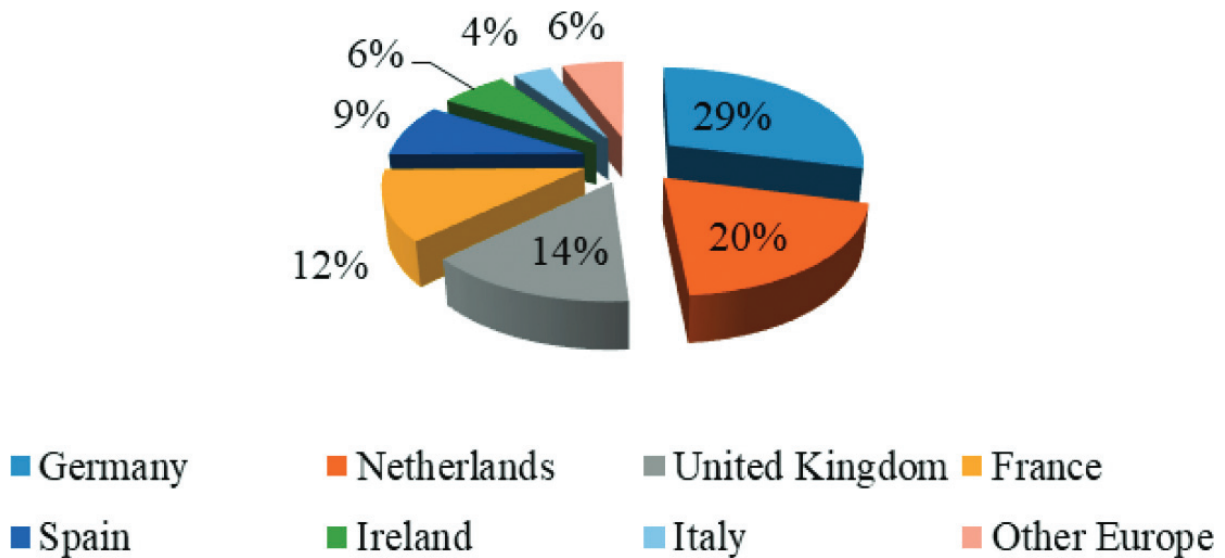


Figure 5. Leading European importers of essential oils (2016, % value). Source: Eurostat.

supplier. The Netherlands is among the leading importers of orange and citrus oils, which offers opportunities for developing countries. The UK plays a large role in the import of oils from other citrus fruits, as well as peppermint and other mints. Developing countries have benefitted most from the UK's consumption of other citrus fruit oils as its growth has been the strongest among citrus in general, and these evolving nations have satisfied half of UK demand. In 2016, France accounted for sizeable shares (12% and 24%) of total EU essential oils import volume and value, respectively. France is a major importer of oils that fall under the HS code 'not elsewhere specified' (nes), which are higher-value oils used in cosmetics. This product group includes a wide range of oils, such as rosemary, *Litsea cubeba*, tea tree, ylang-ylang, and chamomile. The French market is particularly appealing for the specialty oils used in the cosmetics sector and acts as a hub for the industry across Europe. On the contrary, some European countries mainly act as re-exporters and can be useful for getting a producer's essential oils into the European market.

2.2.2. European exports

EU exports reached 41,000 tonnes in 2016, with an average annual 22% increase since 2012. Export value also rose, on average 12% annually, during the same period to approximately €1B in 2016. **Figure 6** indicates the export value of essential oils (both terpeneless and not) from Europe to various regions between 2006 and 2016; **Figure 7** highlights essential oils export volumes from Europe in 2016 alone. The largest European exporters in 2016 were France at 29% by value and the following countries by volume: 26% for the Netherlands, 13% for the UK, 12% for Germany, and 10% for Italy. Together, these countries accounted for 74% of the 2016 European export volume. The 5-year data revealed different European exporters of essential oils (both terpeneless and not) exhibited different trends. While many nations began to trend up in 2009, the Netherlands did not begin to ascend until 2012. On the contrary, Spain and the UK actually decreased in the fifth year. These trends can be explained by the fact that some of the

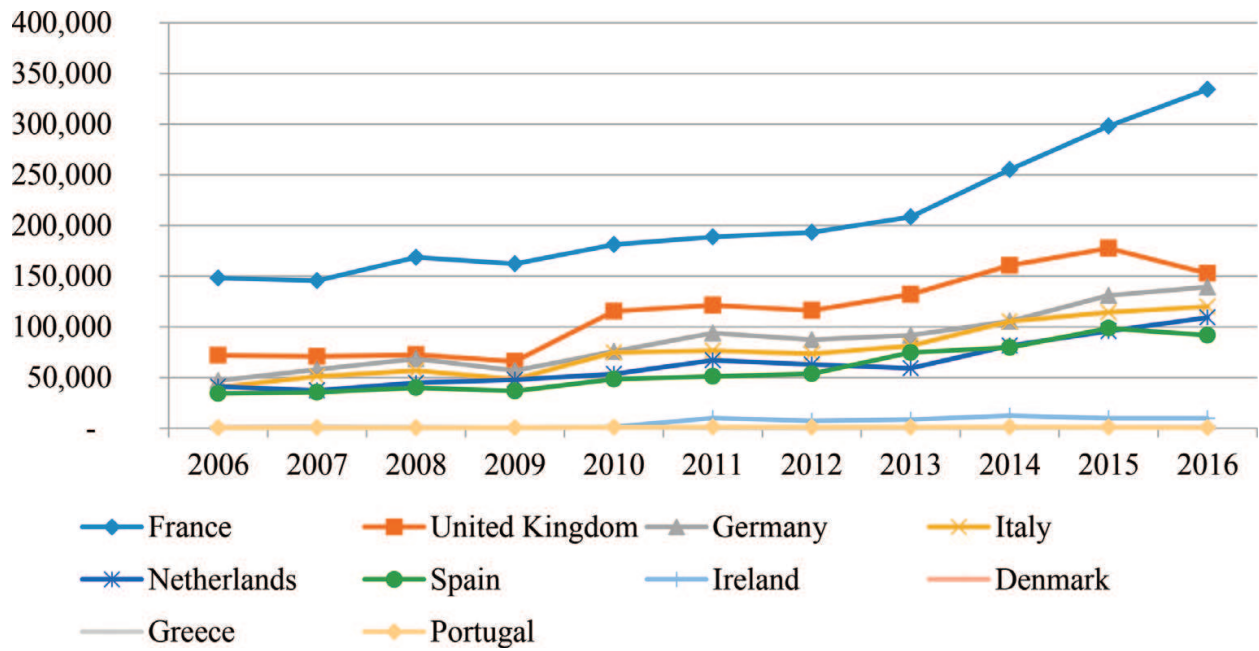


Figure 6. Export of essential oils of the EU-28 (2006-2016; 000s €). Source: EUROSTAT.

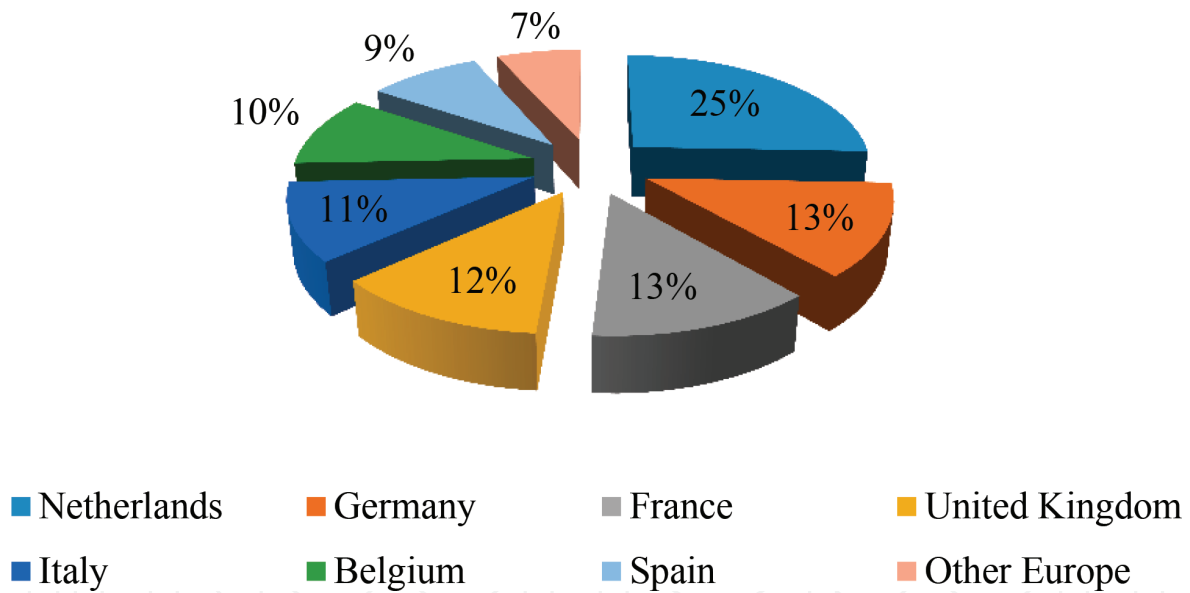


Figure 7. Leading European exporters of essential oils (2016, % value). Source: Eurostat.

countries act mainly as re-exporters (Germany and the Netherlands) who get essential oils to European markets, while others are producers (France and Italy). Of the suppliers, France is the leading supplier of both domestically produced and re-exported high-value essential oils. In recent years, developing countries have played the largest role in essential oils that have limited production in Europe. These include orange (especially, large volume suppliers), 'other mint oils', and 'nes' essential oils. Competition from European sources may be limited for these products, but European producers have many other products for which they can otherwise compete.

2.3. Demand for essential oils

There is a lack of data and information about market demand for essential oils. Demand comes principally from the following markets: food and beverage (35%), fragrances, cosmetics and aromatherapy (29%), household (16%), and pharmaceutical (15%) [3]. Food and beverage is the largest segment in terms of market share, in part due to the recognition that essential oils contain health benefits as the natural ingredients that impart the essence of the source from which they have been derived. Various essential oils used by manufacturers include oils from orange, lemon, and lime. Orange oil is mainly used in foods and beverages to impart a citrus flavour and freshness to the final product. As consumers have become increasingly aware of the health benefits of essential oils, preferences for food and beverage products containing these oils as additives have grown. The global essential oils market has also been driven by the growth in demand for natural and organic hygiene products due to expanding attention to health problems among consumers. Natural flavour and fragrance demand in cosmetics, perfumes, and thermal and relaxation applications are expected to fuel demand for essential oils. Essential oils and oleoresins are not only used in the food processing and industrial seasoning sector in particular but also are important in the flavouring and perfume industry. Globally, operating flavours and fragrance manufacturers are among the main buyers of essential oils. Their sales provide an indication of developments in their market and subsequent demand for essential oils. Between 2012 and 2016, global sales of flavour and fragrance manufacturers increased by 7% to €25B. The growing demand for natural cosmetics and natural flavourings is an important driver of this sales growth. The top 11 companies represent 78% of total sales; the three major flavour and fragrance manufacturers are Givaudan, Firmenich, IFF, which as a threesome account for 46% of all sales (**Figure 8**). In 2016, Frutarom and Mane, SA, continued to accelerate their growth through various acquisitions [38].

2.4. Consumption of essential oils

Consumers are becoming more attentive to their health. Therefore, food and beverage manufacturers are looking to replace unhealthy ingredients that improve the texture of food with natural thickeners. Growing consumer preference for natural products has led to the development of innovative applications in personal care and beauty products as well. Rapid industrialisation and increasing disposable consumer incomes are the other major factors driving essential oil production in the developing countries of China, India, Vietnam, and Thailand. The majority of consumers by country, according to the data provided by Directorate Marketing of the USDA, are in the US (40%), Western Europe (30%), and Japan (7%) [39]. Sales of essential oils are closely tied to consumer education—the more consumers understand how and why to use essential oils, the greater the demand and sales growth. Aromatherapy is a prime example of how market sales are influenced by sector operations. The aromatherapy market relies on both professional (aromatherapists) and personal (individual consumers) utilisation for its retail purchases. In a 2013 survey of trends in the US aromatherapy market, over 62% of professional therapists developed their own products for re-sale in addition to their professional use. Almost all aromatherapists are self-employed, running their own small practices, but many also play roles in the educational (40%) and retail/wholesale (26%) ends of

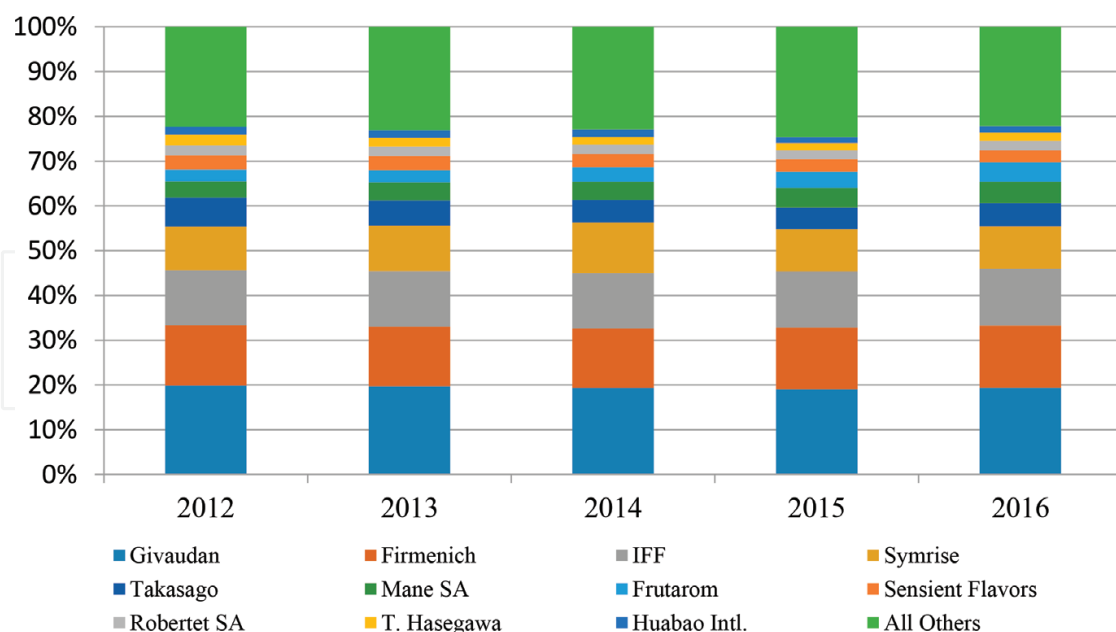


Figure 8. Development of the world’s leading flavour and fragrance manufactures. Source: Leffingwell & Associates.

the industry, which fragments the market into one comprising many small operators. This is reflected in typical purchase volumes, where significant percentages (43%) of oil purchases are in quantities from 0.5 to 1 L/year, as opposed to purchases of 50 L or drums by industry giants. Food flavouring manufacturers are increasingly interested in self-producing flavourings from natural ingredients to meet the demand. Essential oils are some of their most important natural ingredients, and the variety of available essential oils provides many opportunities to formulate new or improved natural flavourings for use in their products. The challenge for such manufacturers is to produce consistent natural flavourings. Compared to synthetic ingredients, essential oils vary more often in composition, which can affect processing characteristics and final product performance.

3. European Union legislation for essential oils

The relevant legislative rules on essential oils are referred to as ‘general regulations’ (known as REACH and CLP) and ‘specific regulations’. Analysed below are general aspects of the principle regulations pertaining to essential oils and those related to individual product categories considered in this chapter (flavourings for food, cosmetics, and additives for animal nutrition).

3.1. General regulations for essential oils

REACH Regulation (Regulation (EC) No 1907/2006 of 18 December 2006) [40–44] concerns the registration, evaluation, authorisation, and restriction of chemicals (in short, ‘substances’). It explicitly references the ‘Sustainable Development Implementation Plan’ (Johannesburg World Summit), which foresees that by 2020 the production and use of chemicals will be such

as to minimise the harmful effects on human and environmental health, as required by the Strategic Approach to the International Management of Chemical Substances (SAICM), Dubai, 6 February 2006. REACH applies to all individual chemicals in preparations, contained in products manufactured or imported in annual quantities above a tonne. Of course, many compounds are excluded from the regulation: radioactive substances, waste, substances subject to customs control, as well as substances used in human or veterinary medicine, in animal foodstuffs, additives in foodstuffs for human consumption, flavourings for human consumption, additives for animal food, and additives for final preparations for end users of medicines, cosmetics products, and substances for which the available data indicate minimal risk exits. A broad category excluded from REACH are substances subject to customs control (in transit or re-export) transported by rail, road, ship, or air. Creation of the Regulation arose from multiple objectives: (1) to protect human and environmental health from the use of chemical products; (2) to encourage or guarantee replacement of dangerous substances with less risky substances or technologies, to incentivise transition to more technically or economically viable alternatives; (3) to instil manufacturers and importers with the responsibility of understanding and managing the risks associated with the use of these substances; (4) to allow free circulation of substances on the EU market through similar requirements in EU countries; (5) to improve competitiveness and foster innovation in the EU chemical industry; (6) to promote the use of alternative methods to assess the substance hazards and limit animal testing. To collect the data and then make it available and useful to interested parties, the Regulation established the 'European Chemicals Agency' (ECHA) to collect, manage, and control manufacturer and importer substance registration. Collected substance and use information may be accessed to assist with activities related to implementation EU rules on voluntary labelling or to guide the EU Commission when they are revising rules concerning such substances, voluntary instruments, or community trademarks. The registration process starts with an assignment of a presentation number (identifier comprising a number and date), plus payment of a tariff. It finishes when the registrant receives notification of registration for the same identifier. The Agency is obliged to notify the EU member state in which the manufacturing site (or registered office of the manufacturer) is located that the following are available in the Agency database: registration dossier, registration date, completeness check results, and other manufacturer-provided information. The manufacturer or importer must update the registration database as needed (e.g. changes in legal status, substance composition, labelling, etc.). The ECHA website [44] hosts all registered substances statistical data under three groupings 'Full Registration', 'Transported Isolated Intermediates' and 'On-site Isolated Intermediate', for the European Economic Area (EEA) that includes the EU member states, plus Iceland, Norway and Liechtenstein. The number of registrations from 1 June 2008 and forward === - categorized as 'Detailed Registration Statics' - is 14,640, of which 75% are 'Full registrations' that represent 6,763 'Substances'. The difference between Registrations and Substances is due to "In one registration dossier any combination of one up to three different types can be covered". The bulk of registrations is made by large enterprises (85%), as compared to small and medium enterprises (SME). In terms of registrant, 43% of registrations are done by importers, 28% by a representative of a non-EU manufacturers, 24% by manufacturers, and 5% by manufacturers/importers. Essential oils are not among the substances most registered by EEA countries; rather, these lists contain the likes of ethanol, propane-1,2-diol, silicon dioxide, and so on. The

second 'general regulation' of interest for essential oils is known as Regulation Classification, Labelling, Packaging (CLP), Regulation (CE) N. 1272/2008 16 December 2008 on classification, labelling, and packaging of substances and mixtures [45]. The law became effective on 1 June 2015 and had several objectives as follows: (1) to determine if a substance or mixture has properties that classify it as dangerous; (2) to ensure high levels of human and environmental health protection; (3) to harmonise classification, labelling, and packaging criteria; (4) to facilitate free circulation of substances, mixtures, and articles; (5) to create a single set of rules to oversee the safe transport of these substances; (6) to produce a catalogue of substances from the classification and labelling of chemicals based on the classification of chemicals used by the United Nations. The regulation requires manufacturers, importers, and downstream users to classify, label, and package dangerous substances or mixtures before market placement, based on a 'self-classification' by manufacturers, importers, and other related parties. Comparison of information on the hazard(s) of a given substance/mixture to information on the dangers established by the criteria of the CLP Regulation results in a class and category danger assignment that correlates with the related physical, human, and/or environmental health hazard(s). Hazards must be communicated and maintained via appropriate labelling throughout the supply and production chain to market for substances classified as dangerous, mixtures containing one or more substances classified as dangerous beyond a specified threshold and for articles having explosive properties. Label elements—pictographs, warnings, and standard declarations of danger, prevention, reaction, storage, and disposal—are precisely defined for each hazard class and category. In addition, the name, address, and telephone number of the supplier are provided. Packaging must be such so as to prevent escape of the contents, not attract the attention or curiosity of children, and look similar to that typically used for food, animal feed, or cosmetics. Classification and labelling of certain hazardous substances are standardised across the EU (CLH) and are found in Annex 6 of regulation classifications. The following situations allow any manufacturer, importer, downstream user, or member state to propose standard classification and labelling: (1) when a substance is carcinogenic, mutagenic, or toxic to reproduction or respiration; (2) when classification of a substance is necessary at the European level for other hazardous classes; (3) when it is necessary to add one or more hazardous classes to an existing item. Manufacturers and importers are fully responsible to keep current any classification and labelling information for substances they place on the market in a specific C&L inventory maintained by ECHA. The regulation is also the basis for legislation that manages chemical risks.

3.2. Regulations inherent to some uses of essential oils

The following paragraphs describe the principal contents of regulations inherent to flavourings, cosmetics, and additives for animal nutrition. In general, regulations aim to protect consumer health and to improve the free circulation of stuffs in the EU market through common rules.

3.2.1. Flavourings for food

Regulation (EC) No 1334/2008 of 16 December 2008 is the centrepiece legislation 'on flavourings and certain food ingredients with flavouring properties for use in and on foods' [46].

It aims to protect human health and to allow free movement of food on the EU internal market. For regulation purposes, 'flavouring' is a product that is not consumed as such, but is added to food to modify its taste or aroma and is manufactured or derived from substances of plant, animal, or microbiological origin. 'Natural flavourings' are substances normally present in nature; they fall outside the scope of the legislation in the following cases: raw foods, substances with sweet, sour, or salty tastes, and mixtures like spices or herbal teas. Instead, the regulation targets flavourings used in and on foods, flavouring food ingredients, foods containing flavourings, and the basic materials for their preparation. According to Article 4 of the regulation, "flavourings/flavouring ingredients may be used only if they do not present a risk to the health of the consumer on the basis of the available scientific data and if their use does not mislead the consumer". The safety requirement demands that a risk assessment be made prior to the use as envisaged; a complementary section of the regulation, Article 8, indicates the flavouring aromas and food ingredients excluded from risk assessment and authorisation. Risks are assessed under a Commission of the Food Safety Authority (EFSA). Aromas and base material flavourings that are evaluated and authorised by the Commission are added to the EU list that allows their market entry as such or for food use. Articles 14, 15, 16, and 17 specify label standards for intermediate users and end-users sales. For market placement for intermediate users, the package or container must display aroma, food, name, company name, and address of the producer, while flavourings for final consumer use can be placed on the market only if 'for food' is present on the label, easily visible, legible, and indelible. When the product is 'natural', additional provisions apply. Finally, Article 20 of the regulation expects member states to create monitoring systems for flavouring consumption use and information collection to the Authority and Commission.

3.2.2. *Cosmetics*

The foundational legislation for the cosmetics sector is Regulation (EC) No 1223/2009 of 30 November 2009 [47, 48]. Essential oils are contained in many cosmetics (e.g. creams or body care products). Rules regulating the use of essential oils in cosmetics aim to balance EU market placement while considering the technological innovation in the sector. Another objective is to guarantee high quality to protect the health and safety of consumers. The regulation became effective on 1 July 2013. It contains many essential aspects: 'Basic definition set' (cosmetics, substances, manufacturers) and of the Responsible Person; specifications for labelling and advertising claims; indications for centralised notification; rules concerning animal testing; manufacturing standards (GMP); responsibilities of member states for market surveillance; indications relating to carcinogenic, mutagenic and toxic for reproduction (CMR) substances and to nano-materials. The Responsible Person (natural or legal person) is obligated to meet the regulatory requirements for each cosmetic product on the market. The individual is held to both technical and health responsibilities and must submit all security documentation from Information Documentation to Safety Reports (Annex I of the Regulation) to Safety Assessments. In addition, organised 'surveillance of cosmetics' and health authority reporting must be established. There must be a guarantee of traceability to identify the links within the supply and distribution chain for three years following the date of distribution availability. If a

cosmetic presents 'non-conformities', the Responsible Person must make the cosmetic compliant, withdraw it from the market, or recall it from all member states where it is available. The label must be void of words or other means that suggests characteristics or functions the product does not possess. The label must include the company name and address of the Responsible Person; country of origin of imported products; nominal content for packaging by weight or volume; expiration date for products properly stored; precautions for use; the manufacturing lot number or reference allowing identification of the product; ingredient list, substances, or mixtures used intentionally during manufacture. In terms of product claims, the regulation indicates that the Commission should define an 'Action Plan' to standardise the declarations applied to cosmetics and that it should set common criteria for the use of those declarations. A centralised information source provides distributor names, label dispatch, and product photographs and creates a master registration list for all EU member states. Animal product testing is under replacement in the EU with alternative methods. Animal testing is already prohibited for finished products, ingredients, and combinations of ingredients. Consequently, EU cosmetics market placement of products with formulation or ingredients or combination of ingredients is not permitted. Member states are responsible for verifying the application of manufacturing principles through ISO 22716 'Guidelines on Good Manufacturing Practices' (GMP). Member states must also monitor the market with information provided by sector operators, random testing, and ingredient lists aimed at allergic sensitivities, in particular.

3.2.3. Additives for animal nutrition

There are two regulations governing additives for animal nutrition: one is Regulation (EC) No 1831/2003 of 22 September 2003 on additives for use in animal nutrition and the other is Regulation (EC) No 429/2008 of 25 April 2008 that details the rules for the implementation of the former regulation (Regulation (EC) 1831/2008) [49–51]. Article 2 of the regulation defines feed additives as "substances, micro-organisms or preparations, other than feed and pre-mixtures which are intentionally added to animal feed or water in order to perform, in particular, one or more of the functions". Five different categories of additives are identified: technological, organoleptic, nutritional, zoo-technical, coccidiostatic, and histomonostatic. The first three categories include 'functional groups' as highlighted in Annex I of the regulation itself. It clearly states that as of 1 January 2006, antibiotics are prohibited as feed additives and that only additives authorised according to Regulation 1831/2003 and its specific Authorisation Regulation can be placed on the market, used, and transformed. The regulation generally limits market readiness or use of pre-mixes, defined as "mixtures of feed additives or mixtures of one or more feed additives with feed materials or water, used as a carrier, not intended for direct feeding to animals" in the same way as described above. Additives mixtures do not need authorisation under the following circumstances: the operator complies with the requirements of Regulation (EC) No 183/2005, the additive mixture is produced only by authorised additives, and the conditions of use foreseen for each single additive are respected; the chemical, physical and biological compatibility between mixture components is ensured relative to the expected effects. The regulation also provides indications regarding labelling (Article 16). Producers and/or those who place additives and pre-mixtures of additives on the market must be

registered or recognised per Regulation (EC) 183/2005 guidelines. Finally, it should be noted that the authorisation for a new additive (Article 4) or for a new use requires submission of an application to the European Commission—Directorate General for Health and Consumer Protection (DG SANTE), that demonstrates compliance with paragraph 2 of Article 5 and at least one of the characteristics named in paragraph 3 of Article 5. Regulation (EC) No 429/2008 contains preparation and presentation rules for additive application, evaluation, and authorisation. Completed applications are forwarded to the Commission, which sends it to EFSA and to the VII-DGSAF Office of the Ministry of Health for evaluation by the member state Ministry of Health and Community Laboratory. At the end of the evaluation, EFSA issues an opinion (Article 8), which is sent to the EU Commission for preparation of an *ad hoc* regulation. Each authorised additive is entered in a community register with authorisation date, expiration date, and the relative Authorisation Regulation.

4. Conclusions

The first section of this chapter describes, within the limitations of the data, the fundamental aspects of the market for essential oils. *Production* is estimated to reach more than 150,000 tonnes or about \$6B USD in 2017 across the world. The main producers, by continent are China and India (Asia), Morocco and Tunisia (Africa), the USA, Canada, Mexico (Americas), and France and Germany (Europe). As a consequence of growth in consumer interest in natural and healthy living, of a rise in income in developing nations of the world, and of an increase in knowledge and use of essential oils (aromatherapy, spa therapy, and more), demand is expected to expand by 2020. Production often occurs on rural area farms (about 1.6 million farms, 0.6% of the world in total). *World trade* data values exports in excess of \$4B USD and imports above \$4.5B USD in 2016. Europe accounts for about 40% of world exports and it is expected to maintain this market share in the coming years due to the demand for essential oils in various sectors. At the country level, the US, Germany, the UK, and France are the main exporters. The latter three countries are also the main world importers. *Demand* for essential oils worldwide is driven first by companies producing flavourings and fragrances. Growing sales of flavourings and fragrances indicate future demand increases for raw materials (essential oils). The three main companies in the flavouring and fragrance sector are Givaudan, Firmenich, and IFF; combined, they represent 46% of total sales. Consumption is driven by the same factors described above that drive production. The following countries consume the most essential oils in the world: the US (40%), Western Europe (30%), and Japan (7%). The second section of the chapter examines the principal EU regulations governing essential oils. General regulations, known as REACH and CLP, refer to chemical products, which also affect essential oils. EU legislation for specific product uses (flavourings for food, cosmetics, additives for use in animal feed) also relates to essential oils. REACH and CLP concern the registration, evaluation, authorisation, and restriction of chemicals (essential oils included). They have many goals: to protect human and environmental health from the use of chemical products; to instil manufacturers and importers with the responsibility of understanding and managing the risks associated with the use of these substances; to allow free circulation of

substances in the EU market through similar requirements in EU countries; to improve competitiveness and foster innovation in the EU chemical industry; to promote the use of alternative methods to assess the substance hazards and limit animal testing. All substances subject to regulation (waste excluded) must be registered and authorised, as described by these regulations. The European Chemical Agency, established by REACH, oversees application and authorisation for registry admission and ultimate entry into the marketplace. CLP regulates substance and mixture classification, labelling, and packaging. It determines if the properties of a substance or mixture are dangerous. It also ensures high levels of human and environmental health protection, a standard classification schema, labelling and packaging criteria for EU member states, and a catalogue of substances consistent with chemical classification used by the United Nations. Pre-market entry, dangerous substances, and mixtures must be 'self-classified' by manufacturers, importers, and other related parties (downstream users) into a class and category of danger correlated with the related physical, human, and/or environmental health hazard(s). This regulation also details precise information and pictograms for substance/mixture label placement. Specific regulations for flavourings/flavouring ingredients are limited for those not of risk to consumer health on the basis of available scientific data and as long as their use does not mislead the consumer. Risks are assessed under a commission of the Food Safety Authority (EFSA) and enter into an EU list that allows their market entry as such or for use in food. These specific regulations also lay out label standards for intermediate and end-user sales. *Cosmetics-related* legislation aims to guarantee high quality and the health and safety of the consumer. It establishes the concept of a Responsible Person to submit all security documentation, safety reports, and safety assessments. Moreover, the Responsible Person must guarantee product traceability and market surveillance. The regulation also specifies label and advertising claims, rules on animal testing, manufacturing standards (GMP), indications relating to carcinogenic, mutagenic and toxic for reproduction (CMR) substances, and nano-materials. *Additives for animal nutrition* are the most important contents of the related regulation that applies 'only if the additive is authorised according to Regulation (EC) No 1831/2003 and the specific Authorisation Regulation, respecting the conditions set by this rule, can it be placed on the market, used and transformed'. The EFSA is the authority who manages the authorisation under the second principal regulation of interest for the examined products, Regulation (EC) No 429/2008 on "preparation and presentation of applications, evaluation, and authorization of additives".

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Conflicts of interest

The authors have no conflicts of interest to declare.

Notes

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