EUROPEAN UNION REGULATION: VEGETABLE OILS AND FATS

GQSP GLOBAL QUALITY AND STANDARDS PROGRAMME

El futuro es de todos | Gobierno de Colombia

This publication is developed within the framework of the GQSP Colombia - Quality Program for the Chemical Chain in conjunction with ProColombia. The GQSP Colombia is executed by the United Nations Industrial Development Organization (UNIDO) and financed by the Secretary of State for Economic Affairs of the Swiss Confederation (SECO) and the Ministry of Commerce, Industry and Tourism through Colombia Productiva.

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1. Introduction

This technical sheet covers all products exported from Colombia to the European Union under HS codes:

- **151590:** Fixed vegetable fats and oils and their fractions, whether or not refined, but not chemically modified (excluding soya-bean, groundnut, olive, palm, sunflower-seed, safflower, cotton-seed, coconut, palm kernel, babassu, rape, colza and mustard, linseed, maize, castor and sesame oil).
- **180400**: Cocoa butter, fat and oil

This document will allow Colombian exporters to identify and understand the main requirements to export vegetable oils and fats from Colombia (exit requirements), as well as to access the European Union market (entry requirements). The different sections of the document cover all regulatory requirements and buyer requirements for this product group.

Please, note that it is the responsibly of each exporter to verify the regulations applicable to their product and their updates or modifications.

2. Colombian requirements: Exporting Vegetable oils and fats

Colombian exporters must meet a series of conditions before exporting Vegetable oils and fats. Before engaging in the export process from Colombia, the exporter must always be registered at the DIAN[1] (Colombian Tax and Customs Department) adding in their RUT that they are going to export.

Vegetable oils and fats whose end-use is animal or veterinary must obtain a zoo-sanitary certificate by the Colombian Agricultural Institute (ICA)[2] . For food or cosmetics industry end-use, the mandatory sanitary notification will be issued by the Colombian Food and Drugs Administration (Invima)[3] . For medical or scientifically-controlled

1. https://www.dian.gov.co
2. https://www.ica.gov.co
3. https://www.invima.gov.co

ends, the certificate is issued by the ICA or Invima.

In addition, exporters must have all the legal documentation applicable to their product.

3. International regulatory framework

3.1 Convention on International Trade in Endangered Species

The conservation and sustainable use of natural resources is a crucial issue in the international agenda, involving the public and private sectors, as well as civil society. The international market is subject to specific provisions which regulate the trade of threatened flora and fauna species, which are reflected in the European Union legislation.

Exports to the European Union of an endangered species, or its derivatives, need specific export permits issued by Colombia's competent authorities. The regulatory framework, its details and related procedures are explained below:

The Convention on International Trade in Endangered Species or CITES (Washington Convention)[4], is a multilateral treaty aimed at protecting endangered plants and animals. CITES went into force on 1 July 1975 and is directed at ensuring that international trade in wild animals and plants does not threaten the survival of at-risk species in the wild.

In CITES, plant (and animal) species are subject to different degrees of regulation according to three Appendices[5]:

- Appendix I includes species threatened by extinction, for which trade is subjected to stricter regulation, and is only authorised in exceptional circumstances for specimens of wild origin. Commercial trade in wild taken specimens of Appendix-I listed species is generally unallowed.

- Appendix II includes species that are not necessarily now threatened with extinction but may become so unless trade is strictly regulated.

- Appendix III contains species that are subject to regulation within the jurisdiction of a CITES Party and for which the co-operation of other CITES Parties is needed to prevent or restrict their exploitation.

4. https://cites.org/eng/disc/what.php
5. https://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf

CITES covers all parts of derivatives of plant species, unless specifically exempted, including extracts. Extracts are defined in CITES as any substance obtained directly from plant material by physical or chemical means regardless of the manufacturing process. An extract may be solid (e.g. crystals, resin, fine or coarse particles), semi-solid (e.g. gums, waxes) or liquid (e.g. solutions, tinctures, oil and essential oils)[6].

The implementation of CITES within the European Union is governed by a set of regulations known as EU Wildlife Trade Regulations:

Council Regulation (EC) No 338/97[7] (main regulation) on the protection of species of wild fauna and flora by regulating trade therein.

- Commission Regulation (EC) No 865/2006[8] (as amended by Commission Regulation (EC) No 100/2008, Commission Regulation (EU) No 791/2012 and Commission Implementing Regulation (EU) No 792/2012) laying down detailed rules concerning the implementation of Council Regulation (EC) No 338/97.
- Commission Implementing Regulation (EU) No 792/20129 of 23 August 2012 laying down rules for the design of permits, certificates and other documents provided for in Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating the trade thereinand amending Regulation (EC) No 865/2006.

These regulations are directly applicable in the Member States[10] and go beyond CITES-listed species. The main differences between CITES and the EU Regulation are highlighted in the document *The Differences between EU and CITES Provisions in a Nutshell*[11].

The species covered by Regulation (EC) No 338/97 are listed in four Annexes (A to D)[12]:

Annex A:

- All CITES Appendix I species, except where EU Member States have entered a reservation
- Some CITES Appendix II and III species, for which the EU has adopted stricter domestic measures.
- Some non-CITES species.

6. https://cites.org/eng/app/appendices.php
7. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583168086765&uri=CELEX:01997R0338-20200101
8. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1484753534360&uri=CELEX:02006R0865-20190227
9. https://eur-lex.europa.eu/search.html?DTN=0792&DTA=2012&qid=1484753629149&DB_TYPE_OF_ACT=regulation&DTS_DOM=EU_LAW&typeOfActStatus=REGULATION&type=advanced&lang=en&SUBDOM_INIT=CONSLEG&DTS_SUBDOM=CONSLEG
10. https://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf
11. https://ec.europa.eu/environment/cites/pdf/differences_b_eu_and_cites.pdf
12. https://ec.europa.eu/environment/cites/legislation_en.htm

Annex B:

- All other CITES Appendix II species, except where EU Member States have entered a reservation.
- Some CITES Appendix III species.
- Some non-CITES species.

Annex C:

- All other CITES Appendix III species, except where EU Member States have entered a reservation.

Annex D:

- Some CITES Appendix III species for which the EU holds a reservation.
- Some non-CITES species in order to be consistent with other EU regulations on the protection of native species, such as the Habitats Directive and the Birds Directive.

There are very few examples of carrier oil-bearing plants listed in Annex of Regulation (EC) No 338/97. One of the examples, though not relevant to Colombian biodiversity, is Grandidier's baobab (*Adansonia grandidieri*), listed in Annex B.

There are some carrier oil-bearing plants that integrate the list of "Least concern" species[13] of the International Union for Conservation of Nature (IUCN)[14] and whose population is monitored; example: capaíba / copaiba (*Copaifera langsdorffii*) [15].

But these are not listed in the Regulation (EC) No 338/97's annexes and are therefore not specifically regulated.

In order for buyers in the European Union to import species (and derivatives) that are listed in the Annexes, they must arrange permits /notifications according to the specific Annex in which they're listed. **An export permit from the supplying country (Colombia) is also required for species listed in Appendices I and II of CITES (Annexes A and B of the EU regulation), and for Appendix III (Annexes C and D) if the supplying country's government has listed the species in this appendix.**[16]

The import permit is only issued after a copy of a valid export permit from the CITES Authority in the country of export has been received by the competent authority in the EU country.

Exporters in Colombia must begin the export procedure by contacting the Colombian CITES Management Authorities[17], and apply for a CITES export/re-export permit. The permits (import and export or re-export) shall be presented, as originals, to the Customs.

13. https://airmidinstitute.org/blog/conservation-sustainability-of-essential-carrier-oil-bearing-plants
14. https://www.iucn.org
15. https://www.iucnredlist.org/species/19892010/20043600
16. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
17. https://cites.org/eng/parties/country-profiles/co/national-authorities

Export permits must be endorsed, with quantity, signature and stamp, by the competent authority, in the export endorsement block of the document. If the export document has not been endorsed at the time of export, the Management Authority of the importing country in the European Union should liaise with the Colombian authorities to determine the acceptability of the document[18].

More information can be found on the page of the European Commission: *CITES: Permits, Certificates and Notifications*[19].

3.2 Nagoya Protocol

The implementation of the Nagoya Protocol on Access and Benefit Sharing (ABS) has important implications for natural ingredients, including essential oils and resinoids, and their suppliers. Even though the responsibility to comply with the European regulation belongs to the user of the generic resource (i.e. European importer, manufacturer, etc.) Colombian exporters of natural ingredients must understand and comply with the local Access and Benefit Sharing legislation and assist their buyers in achieving compliance. This can be done by developing specific checkpoints and monitoring obligations through the supply chain.

The Nagoya Protocol, on Access and Benefit Sharing (ABS), is an international treaty which has been in force since 2014. Its main objective is the fair and equitable sharing of benefits derived from the use of genetic resources. This means that, when benefits arise from research or development on genetic resources (including when it leads to the commercial use of a developed product), these benefits should be shared fairly and equitably with the country providing these resources[20].

The provisions of the protocol offer legal protection and transparency to both providers and users of genetic resources. Furthermore, they help ensure benefit-sharing, particularly when genetic resources leave the country of origin, and establish more predictable conditions for access to genetic resources.

The European Union is a signatory of the Nagoya Protocol. This means that the European Union as a regional bloc and their individual countries are legally obliged to implement mechanisms and to comply with its principles. These obligations are reflected in business practices in both export and import countries / end markets. As such, Colombian exporters are also expected to comply with the national legislation addressing Access and Benefit Sharing (ABS).

18. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
19. https://ec.europa.eu/environment/cites/info_permits_en.htm
20. https://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

The Nagoya Protocol is implemented in the European Union through Regulation (EU) No 511/2014 of the European Parliament and of the Council, on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union[21].

The regulation holds users of genetic resources or traditional knowledge accountable for exercising and demonstrating due diligence in relation to access to these resources / knowledge. The due diligence process includes compliance with the applicable legislation in countries where the genetic resource is sourced (example: Colombia) in terms of:

- Obtaining prior informed consent (PIC) of the country in which the genetic resource is located before accessing the resource.

- Negotiating and agreeing on the terms and conditions of access and use of this resource through the establishment of mutually agreed terms (MAT).

This due diligence process also implies that users should collect, keep and transfer to subsequent users the information relevant to ensure compliance with the due diligence requirements. Users also have the obligation to declare to the National Competent Authorities of their Member State that they exercised due diligence, at the end of utilization. This declaration is called Due Diligence Declaration (DDD)[22].

The European Commission has published the *Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union[23] (Horizontal Guidance) with the purpose to help users to comply with the requirements of Regulations (EC) 511/2014 and (EC) 2015/1866*. The regulations apply to derivatives such as essential oils and resinoids. According to the EC Horizontal Guidance, “access to derivatives is covered when it also includes genetic resources for utilization, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained.”[24]

21. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511
22. https://ifrafragrance.org/docs/default-source/guidelines/nagoya-protocol-guidance/il1090-09-04-2020-ifra-iofi-guidance-document-on-nagoya-protocol-and-abs-regulations-(att-03)-european-union-(april-9-2020).pdf?sfvrsn=50a72c37_6
23. https://op.europa.eu/en/publication-detail/-/publication/aefa4237-5477-11eb-b59f-01aa75ed71a1/language-en
24. https://ifrafragrance.org/docs/default-source/guidelines/nagoya-protocol-guidance/il1090-09-04-2020-ifra-iofi-guidance-document-on-nagoya-protocol-and-abs-regulations-(att-03)-european-union-(april-9-2020).pdf?sfvrsn=50a72c37_6

4. EU: Chemicals legislation

4.1 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Regulation (EC) No 1907/2006 of the European Parliament and of the Council[25], is a regulation of the European Union which was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry[26]. This regulation requires the industry to have sufficient knowledge about the properties of their substances and to manage their potential risks.

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for several years with insufficient information on the hazards that they pose to human health and the environment[27].

A “substance” is defined in REACH[28] [29], as: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition[30].

REACH has consequences mainly to Natural Complex Substances (NCS) of botanical origin used in cosmetics. The NCS are described by ISO 9235:20138 (Aromatic Natural Raw Materials)[31].

Vegetable oils and fats obtained from natural and non-chemically modified sources are exempt from REACH obligations, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC, with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or a combination thereof[32].

Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths; for example they can be rich in palmitic, oleic or linoleic acid [33].

25. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
26. https://echa.europa.eu/regulations/reach/understanding-reach
27. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm
28. https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32006R1907&from=EN
29. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm
30. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
31. https://echa.europa.eu/documents/10162/13643/efeo_ifra_guidelines_es.pdf/c85bc8c4-f71a-48ac-8b94-607be5cc4950
32. https://ec.europa.eu/environment/chemicals/reach/pdf/8_draft_guidance_5.pdf
33. https://echa.europa.eu/documents/10162/23047722/annex_v_draft_changes_10032010clean_en.pdf/ec640502-11c2-4ac6-b08f-1180f948f1fa

Isolated compounds of vegetable oils (example: fatty acids, esters, residues) may need to be registered.

In addition, the registration and authorization requirements of REACH do not apply to substances traded in quantities lower than one tonne by one specific company, or used in[34]:

- Scientific research and development.
- Food and feed.
- Medicinal products.

The website of the European Chemicals Agency (ECHA) *Understanding REACH* [35] explains in detail the process of Identification, Registration, Evaluation and Authorization / Restriction of substances. In addition, the website *Information on Chemicals* [36] contains the full list of substances.

4.2 Classification, Labelling and Packaging (CLP)

The Globally Harmonized System (GHS) of Classification and Labelling of Chemicals[37] is a system developed at the United Nations level to standardize and harmonize the management of chemicals globally. The United Nations Purple Book[38] is a guide on the implementation of the GHS which:

- Defines the physical, human health and environmental hazards and harmonizes the criteria for their classification according to these hazards;
- Standardizes the content and format of the chemical substances' labelling and Safety Data Sheets (SDS).

The GHS is governed in the European Union through Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.[39]

Vegetable oils and fats are generally not classified as hazardous substances, thus the regulation on Classification and Labelling of Chemicals (CLP) does not apply, regardless of the quantities traded.

However, it is recommended that exporters consult the website of ECHA, specifically the REACH[40] and CLP[41] databases) for their

34. https://echa.europa.eu/support/getting-started/am-i-exempt
35. https://echa.europa.eu/regulations/reach/understanding-reach
36. https://echa.europa.eu/information-on-chemicals
37. https://unece.org/about-ghs
38. https://unece.org/ghs-rev8-2019
39. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272
40. https://echa.europa.eu/information-on-chemicals/registered-substances
41. https://echa.europa.eu/information-on-chemicals/cl-inventory-database

specific vegetable oil or fat. In case this vegetable oil or fat is considered to be hazardous, the following section applies: *Classification and labelling*.

Classification and labelling

Regulation (EC) No 1272/2008 defines the content and presentation of the label. The label must be firmly attached to one or more of the packaging's surfaces and has to include the following information (as per Article 17):

- The name, address and telephone number of the supplier.
- The nominal quantity of a substance or mixture in packages made available to the general public, unless this quantity is specified elsewhere on the package (if applicable).
- Product identifiers (example: EC number, CAS number).
- Where applicable (i.e. for hazardous substances), hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation[42].

Article 17 of Regulation (EC) No 1272/2008 also establishes that the label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Articles 31 to 33 of the Regulation (EC) No 1272/2008 addresses the rules governing the applicable of labels:

- Labels shall be readable horizontally when the package is set down normally.
- The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.
- The label elements shall be clearly and permanently marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.
- The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.
    - Hazard pictograms shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible.

42. https://echa.europa.eu/es/regulations/clp/labelling

- Hazard pictograms shall be in the shape of a square set at a point. Each hazard pictogram shall cover at least one fifteenth of the surface area of the harmonized label but the minimum area shall not be less than 1 cm^2.

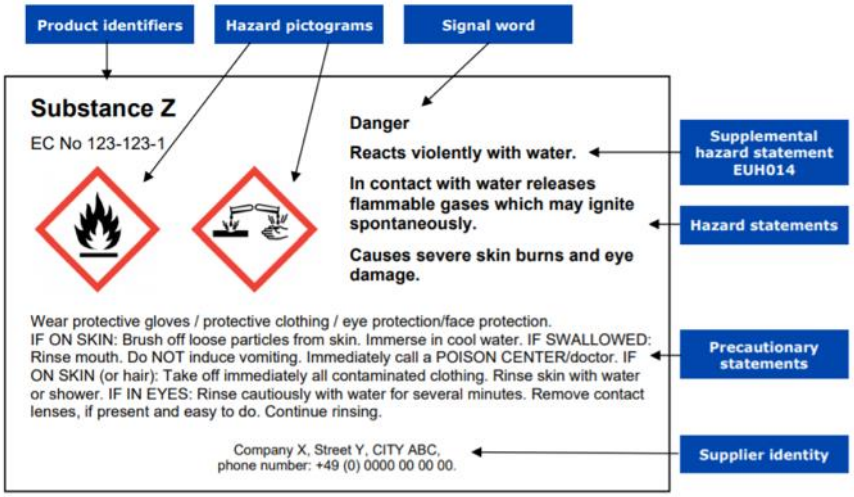
- The dimensions of the label shall be as follows:

Capacity of the package	Dimensions of the label, in milimeters
Not exceeding 3 liters:	If posible, at least 52 x 74
Greater than 3 liters but, not exceeding 50 liters:	At least 74 x 105
Greater than 50 liters but not exceeding 500 liters:	At least 105 x 148
Greater than 500 liters:	At least 148 x 210

- The hazard pictograms, word of caution / signal word, hazard statements and precautionary statements shall be located together on the label.

The European Chemicals Agency (ECHA) has a detailed document, the *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008*[43], provides step-by-step instructions on how to comply with this regulation. It also contains a few examples of generic labels complying with the CLP requirements, such as:

43. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65



(a) inner packaging for supply

(b) outer packaging for supply

(c) transport packaging

Source: Guidance on labelling and packaging in accordance with Regulation (EC) Nº 1272/2008.
Version 4.2. March 2021

You can find an elaborate definition of the flammability, risk phrases and safety phrases in Directive 2001/59/EC[44]. The Directive provides technical information for implementing European Union regulation on Classification, Labelling and Packaging. In addition, the database of the *C&L Inventory*[45] on the website of the European Chemicals Agency (ECHA) contains all the necessary information on the classification and labelling of the substances which have been notified and registered by manufacturers and importers in the EU.

Most pure vegetable oils and fats are inherently safe ingredients when used in cosmetics and are not considered hazardous. Therefore, their labels do not need to include hazard statements, labelling phrases, signal words and pictograms.

For hazardous substances, the classification and labelling information for specific substances must also be included in the *Safety Data Sheets* (SDS), regulated in the European Union by Annex II of the REACH regulation[46] which contains the necessary data that an SDS must have.

For transport purposes and for forward sales to the European manufacturing industry, buyers of vegetable oils and fats may also require an SDS containing the 16 sections established by the Globally Harmonized System. This may happen even if the vegetable oil or fat is not considered hazardous[47].

5. EU: Cosmetics legislation

In the European Union, cosmetic products are regulated by Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products[48]. The regulation requires the responsible person to safeguard that the cosmetic product has gone through a basic safety assessment based on relevant technical information before the product can be marketed in the European Union. In addition, a product safety report has to be prepared according to Annex I of this regulation. The guidelines for Annex I are set out in Commission Implementing Decision 2013/674 / EU[49].

The cosmetics regulation mainly focuses on finished cosmetics products, but has consequences for suppliers of natural ingredients such as essential oils and resinoids, particularly.

44. https://eur-lex.europa.eu/legal-content/ES/TXT/HTML/?uri=CELEX:32001L0059&from=RO
45. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/
46. https://echa.europa.eu/regulations/reach/legislation
47. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient#preparing-the-safety-data-sheet-sds
48. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
49. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D0674

Annexes II and III establish that the responsible individual or company in the European Union (importer, agent, manufacturer, etc.) must safeguard compliance to the legal requirements. However, this means that non-EU ingredient suppliers have the direct responsibility to support the responsible person or company in complying with its various provisions, as detailed in the next sections. [50]

CosIng database

CosIng is the European Commission database for information on cosmetic substances and ingredients contained in the:

- Cosmetics Regulation (EC) No 1223/2009 of the European Parliament and of the Council.[51]
- Cosmetics Directive 76/768/EEC (cosmetics directive), as amended.[52]
- Glossary of common ingredient names for the purpose of labelling cosmetic products placed on the market (as established by Decision (EU) 2019/701 of 5 April 2019).[53]

The Cosmetic Ingredient (CosIng) database[54] has two sections:

- Section 1 - It consists of all the cosmetic ingredients, except perfume and aromatic raw material.
- Section 2 - It consists cosmetic ingredients related to perfume and aromatic raw material.

The CosIng database contains information on the ingredient's identity, notably identifiers such as INCI name, Ph. Eur., INN, IUPAC, and their chemical names; its registration numbers according to EINECS/ELINCS, CAS; its function(s) in cosmetics and all mandatory restrictions, conditions of use and warnings.

The database does not constitute a list of ingredients necessarily authorized for use in cosmetic products, although they have been assigned with an INCI name (International Nomenclature Cosmetic Ingredient)[55]. The qualification of a product is to be decided by the national competent authorities, under the supervision of the courts, on a case-by-case basis, taking into account all the characteristics of the product. In addition, the use of any ingredient in cosmetic products must be supported by a safety assessment of the product.[56]

50- https://www.aemps.gob.es/publicaciones/publica/docs/Guia_Aceites_Esenciales.pdf?x42633
51. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223
52. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31976L0768
53. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0701&from=EN
54. https://ec.europa.eu/growth/sectors/cosmetics/cosing_en
55. https://ec.europa.eu/growth/tools-databases/cosing/layout/CosIng_Manual.pdf
56. https://ec.europa.eu/growth/sectors/cosmetics/cosing_es

If an ingredient is not registered in CosIng, it may still be listed in the cosmetic product using its INCI name.

5.1 Cosmetic Products Regulation, Annex II – Prohibited Substances

Annex II of Regulation (EC) No 1223/2009 contains substances which are banned from use in any cosmetic products marketed for sale or use in the European Union. Among the 1,640+ substances listed in this annex[57], there are no specific vegetable oils and fats listed.

The complete list of prohibited substances can be found in Annex II, and its updates are available on the platform of the *European Chemicals Agency: Cosmetic Products Regulation, Annex II - Prohibited Substances.* [58]

5.2 Cosmetic Products Regulation, Annex III - Restricted Substances

Annex III of Regulation (EC) No. 1223/2009 lists substances whose use in cosmetic products in the European Union is banned, except under certain conditions; i.e. field of application or use, maximum allowable concentration limits in finished products, and any additional limitations.

Examples of restricted substances related to vegetable oils and fats originate mainly from peanut oil:

- Hydrogenated peanut oil: CAS number 68425-36-5, EC number 270-350-9, with a maximum concentration of peanut proteins of 0.5ppm in all cosmetic products. [59]
- Peanut oil extracts: CAS number 8002-03-7; EC number 232-296-4, with a maximum concentration of peanut proteins of 0.5ppm in all cosmetic products. [60]

The complete list of substances whose use in cosmetic products in the European Union is banned, except under certain conditions of Annex III and its updates are available on the platform of the *European Chemicals Agency: Cosmetic Products Regulation, Annex III - Restricted Substances*. [61]

5.3 Cosmetic Products Regulation, Annex IV – Allowed Colorants

Not relevant for vegetable oils and fats.

57. https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf
58. https://www.echa.europa.eu/cosmetics-prohibited-substances
59. https://echa.europa.eu/substance-information/-/substanceinfo/100.063.936
60. https://echa.europa.eu/substance-information/-/substanceinfo/100.029.359
61.. https://echa.europa.eu/cosmetics-restricted-substances

5.4 Cosmetic Products Regulation, Annex V – Allowed Preservatives

Not relevant for vegetable oils and fats.

5.5 Cosmetic Products Regulation, Annex VI – Allowed UV Filters

Not relevant for vegetable oils and fats.

6. Other standards

The physical, organoleptic, chemical and chromatographic characteristics of vegetable oils are set by industry. Buyers, especially buyers of commodity oils, will provide suppliers with their own purchasing specifications. These include organoleptic and other identifying characteristics of the oil, fatty acid composition, documentation requirements and packaging conditions.

In addition, buyers can refer to various ISO standards regarding vegetable oils and oilseeds, especially for use in food products [62]. The subjects covered by these standards range from nomenclature and sampling to analysis and determination of various compounds of vegetable oils. For example, determination of saponification value, fatty acid composition and detection and identification of antioxidants.

COSMOS

The COSMOS standard covers all aspects of the sourcing, manufacturing, marketing and control of cosmetic products.

Products that are COSMOS certified must be formulated using only ingredients that the standard allows. Raw materials must be certified or approved: Certified ingredients are organic, while approved raw materials are not organic [63]. The complete list of COSMOS-certified cosmetic products can be found in the database: *COSMOS-certified cosmetic products* [64].

NaTrue

NaTrue is also a certification that experiences growth in the European cosmetics market, although not as widely as COSMOS, but equally applicable to both ingredients and finished cosmetics.

The different certification steps are described on the NaTrue website and with documents available in Spanish [65].

62. https://www.iso.org/committee/47936/x/catalogue/
63. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
64. http://cosmos-standard-rm.org/data/indexcp.php
65. https://natrue.org/uploads/2019/05/ES-NATRUE-Label_Requirements_V3.8-1.pdf

The standards include elements such as: prohibition of animal testing, organic production and labeling, prohibition of the use of Genetically Modified Organisms (GMOs), respect to biodiversity, etc.

7. Quality and safety requirements

7.1 Environment, Health and Safety

Prior to starting a commercial relationship with a new supplier of ingredients, buyers in the European Union normally implement a supplier questionnaire to assess their Standard Operating Procedures (SOPs) regarding environment, health and safety – as well as general quality management in the manufacture of ingredients. This assessment is carried out differently by each company and it is part of an internal process. It is also part of a trust-building process between buyer and supplier. The supplier questionnaires may include subjects such as:

- Information about the company: year of foundation, address, contact information, location of the manufacturing site, type of company, main activities.
- Process of raw material sourcing and approval of suppliers.
- Implementation of Good Agricultural Practices.
- Production capacity.
- Company's organigram.
- Experience / track record in international markets.
- ISO 9001 or the implementation of equivalent processes.
- Format and frequency of internal audits.
- Tools and instruments for quality management.
- Customer management processes.
- Processes of compliance with the regulatory framework of international markets.
- Capacity to comply with documentation obligations, such as technical data sheets, certificates of analysis and safety data sheets.
- Capacity to comply with REACH regulation.
- Processes of testing and verification of products to ensure compliance with applicable regulatory requirements and performance standards.
- Processes of verification, maintenance and calibration of machinery.
- Existence of an in-situ laboratory and its accreditations.
- Control processes related to: allergens, contaminants, foreign materials, stock segregation, packaging and shipping of products.
- Cleaning schedules for: warehouse, manufacturing plant, packaging area.
- Recall processes and contingency plans.
- Implementation of health and safety policies.

- Implementation of a system based on the principles of hazard analysis and critical control points (HACCP) + HACCP flow chart.
- Implementation of other systems for quality and safety management: ISO22000 / FSSC22000, IFS, BRC, etc. / Good Manufacturing Practices (GMP); ISO 22716 (Cosmetics – Good Manufacturing).
- Procedure for reporting of accidents on site.
- Fire safety plan.
- Personal Protective Equipment (PPE) plan.
- Pest control plan.
- Implementation of organic certification.
- Registration in sustainability platforms such as SEDEX, etc.
- Implementation of a corporate social responsibility policy or code of conduct, supported by certifications such as SA8000.
- Certifications such as fair trade (Fairtrade, Fair for Life), and other: FairWild, UEBT, etc.
- Employee training programs.
- Certifications for environmental management such as ISO14000.
- Implementation of internal environmental policies.

The Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts[66], compiled by Andrew Jones (Fair Venture Consulting)[67] and ProFound – Advisers In Development[68] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[69] has a few examples of supplier's questionnaire formats that are implemented by European buyers.

For instance:

Do you have a documented Quality Management System? If yes, how often is it reviewed? *Please include a copy of the index page or Standard Operating Procedure (SOP) and outline content of SOP*
How do you approve your raw material suppliers? *If referring to a SOP, please provide a copy or outline of content of SOP*
Do you have formal risk assessments such as HACCP systems in place? *Please also provide a flowchart*

Raw material production

Buyers in the European Union may expect their suppliers of essential oils and resinoids to guarantee that the botanical raw material used in the manufacturing of these ingredients comply with Good Agricultural Practices (GAP), based on the principles of risk analysis and prevention, Integrated Pest Management (IPM) and

66. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
67. https://www.fairventure.com
68. https://thisisprofound.com
69. https://www.cbi.eu

Integrated Crop Management (ICM).

There is also an interesting growth among European buyers in the demand for organic-certified essential oils and resinoids, which requires compliance with Regulation (EU) No 2018/848 of the European Parliament and of the Council on organic production and labelling of organic products. Organic certification is often perceived as a guarantee of product safety, since it lowers the risks of cross-contamination by pesticides and other impurities.

Manufacturing

At the manufacturing level, buyers of essential oils and resinoids in the European Union expect suppliers to implement a system based on Hazard Analysis and Critical Control Points (HACCP). This is a minimum requirement for food ingredients (example: cooking / edible oil), but it is also commonly applied for cosmetics ingredients, especially when the product has microbiological parameters or specifications.

Additional certifications covering quality management, and which are internationally recognized, such as ISO 9001, also contribute to the reputation of a natural ingredient supplier and can represent a competitive advantage especially among larger (multinational) buyers.

The implementation of Good Manufacturing Practices (GMP) for natural ingredients for cosmetics, based on the guidelines of the European Federation for Cosmetic Ingredients (EFfCI) could also be an additional competitive advantage. However, there are costs involved, and European buyers will not always require it. Before engaging in such initiatives, consult the relevance with your potential European buyer.

7.2 Documentation requirements

The documentation requirements for different natural ingredients for cosmetics like vegetable oils and fats varies widely according to the level of knowledge / familiarity of a specific ingredient to the European market and to a specific European buyer. If an ingredient is well-established on the European market, the efficacy and safety data are most probably well studied and understood, and a supplier will not have to conduct further tests.

However, if a supplier is introducing new ingredients to the market, they will have to compile a **ingredient dossier** which contains and evidences all its safety and efficacy data prior to its introduction to the market. The data used in the compilation of a dossier

are derived from a supplier's own research and/or from secondary sources of public domain; example: the safety and efficacy of your ingredient, history of use, production methods and any other relevant information[70].

A useful guide for the preparation of a dossier for natural ingredients for cosmetics is the **Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts**[71], compiled by Andrew Jones (Fair Venture Consulting)[72] and ProFound – Advisers In Development[73] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[74].

This guide explains the different elements which a dossier should contain.

The 3 essential documents required by buyers of vegetable oils and fats in the European Union are[75]:

- *Technical Data Sheet (TDS)*
- *Certificate of Analysis (CoA)*
- *Safety Data Sheet (SDS*)

Even though vegetable oils and fats are not classified as hazardous substances, buyers may still require a Safety Data Sheet for transport purposes and for sale to a European manufacturer.[76] The SDS will contain the 16 sections established by the Globally Harmonized System, possibly containing precautionary statements that are not prescribed by legislation.

Suppliers of vegetable oils and fats also need to pay attention to the protein content in their oil, as these can cause allergic reactions, as well as other undesirable components that may be present.

The information that must be included, as well as the instructions on how to prepare these documents, can be found on the **Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts**[77]. In general, the content of these 3 documents for vegetable oils and fats consists of the following elements:

70. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
71. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
72. https://www.fairventure.com
73. https://thisisprofound.com
74. https://www.cbi.eu
75. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient#setting-up-your-dossier
76. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient#setting-up-your-dossier
77. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient

Technical Data Sheets (TDS)	Certificate of Analysis (CoA)	Safety Data Sheets (SDS)
• Product Name, INCI Name • CAS number • EINECS number • Tariff heading • Short description of the manufacturing process • Aspect • Humidity • Free fatty acids • % impurities • Specific weight • Fatty acid profile • Microbiological contamination / parameters • Phthalates • heavy metals • Pesticide residues (periodic, not for each batch) • Protein content and allergen declaration • Iodine index • Saponification index Peroxide index • Refractive index • Stability (Rancimat) • Color (Lovibond) • smell • Type and concentration of preservatives • Toxic components (names, concentration) when applied • Life • Type of packaging • Recommended storage • Access permission and other certificates	• Product Name, INCI Name • CAS number • EINECS number • Tariff heading • Short description of the manufacturing process • Aspect • Humidity • Free fatty acids • Specific weight • Fatty acid profile • Microbiological contamination (usually absent) • Tocopherols and other antioxidants (periodic, not for each batch) • Phthalates (periodic, not for each batch) • Heavy metals (newspaper, not for each batch) • Pesticide residues (periodic, not for each batch) • Protein content and allergen declaration • Iodine index • Saponification index • Peroxide index • Refractive index • Stability (Rancimat) • Color (Lovibond) • Smell • Toxic components (names, concentration) when applied • Packaging type	• Product Name, INCI Name • CAS number • EINECS number • Tariff heading • Ignition point • Toxic components (names, concentration) when applied • Studies, reports, published references on safety and efficacy of the substance • Toxicological tests • Local toxicity • Primary skin irritation • Eye irritation • Allergenicity • Sensitization • Systemic toxicity • Mutagenesis: Ames Test • Acute toxicity • Efficacy studies (own, published) • Summary of efficacy data • Security Data Summary • Recommended conditions of use: product type, body part, frequency of use, method of application, concentration in cosmetic products • Environmental data **This information must be compiled and presented according to the 16 sections of the Globally Harmonized System (GHS)[78].**

Other documentation which may be required by EU buyers of vegetable oils and fats include:

- *Animal Non-Testing Declaration* Note that the article 4a (2.3) EU cosmetics directive provides the regulatory framework for the phasing out of animal testing for cosmetics purposes, applicable both to ingredients and finished products[79].
- *Allergen declaration.*
- *CMR declaration (non-mutagenic, carcinogenic, toxic).*
- *BSE/TSE declaration.*
- *Heavy metals declaration.*
- *Non-Nanoparticles declaration.*

78. https://echa.europa.eu/documents/10162/23047722/guidance_sds_v40_peg_en.pdf/42dc8be5-b033-3062-8ee8-6d3a1b8dcb99
79. https://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en

7.3 Packaging and Transport

As vegetable oils and fats are not considered hazardous substances, the use of packaging approved by the United Nations is not a basic requirement, unlike for transportation of essential oils and extracts, for example [80]. In general, vegetable oils and fats are packed and transported in different types of bulk containers, according to the volumes transported.

The largest volumes of vegetable oils are mainly transported in containers for the transport of bulk products / Intermediate bulk containers (IBC) or flexible tanks /flexitanks. Although some buyers prefer ISO-stainless steel tanks (manufactured under the Standards of International Organization for Standardization – ISO) [81], the availability of such containers is generally low in producing countries.

The smaller volumes are transported in metal cans or drums of high-density polyethylene (HDPE). For special, cold-pressed, high-quality vegetable oils (e.g. sacha inchi oil), buyers can demand transportation in stainless steel barrels that optimize the oil's protection from light and air and prevent oxidation.

Vegetable fats, such as shea and cocoa butter, are packed and transported in blocks of 25 kg inside refractory cartons coated with polyethylene or plastic. These cartons are placed on wooden pallets for bulk transport. In some cases, fats can also be transported in liquid (melted) state, ensuring the stability of the fat with previous technical studies that guarantee the quality and useful life of the fat.

FEDIOL, the European Federation of Oils and Oilseeds, has specific guidelines for the packaging and transport of vegetable oils and fats for food use: FEDIOL Code of Practice for the transport in bulk of oils into or within the European Union (Oils and fats which are to be (or likely to be) used for human consumption)[82]. European companies will commonly demand the same standards for vegetable oils for cosmetic use; not only because many companies have both food and cosmetic industries, but also to ensure the highest levels of safety and safety of their ingredients.

8. Final recommendations

- Read more about the regulatory framework, buyer requirements and market developments for vegetable oils and fats in the European Union:

80. https://unece.org/rev-21-2019
81. https://www.iso.org/ics/55.140/x/
82. https://www.fediol.eu/data/14COD152%20COP%20Transport%20in%20bulk%20of%20oils%20into%20or%20within%20the%20EU.pdf

- Centre for the Promotion of Imports from Developing Countries (CBI): Market Information on Natural Ingredients for Cosmetics.[83]
- Import Promotion Desk (IPD): Market Information on Essential Oils and Vegetable Oils. [84]

- Consult official data sources in the European Union to learn more about the regulatory requirements:

  - European Commission[85]
  - EUR-LEX[86]
  - Access2Markets[87]
  - The European Chemicals Agency (ECHA)[88]

- Comply with the minimum legislative requirements for vegetable oils and fats in the European Union:

  - Do not export threatened species, and their derivatives, which are listed in CITES or in the Annexes of the European Union's Wildlife Trade Regulations, or comply with the necessary export permits. Note that very few carrier oil-bearing species are listed under these Annexes. Follow any future updates to the species listed in these Annexes by directly accessing Regulation (EU) No. 1320 / 2014 [89] and the Species+ website of the United Nations Environment Programme - World Conservation Monitoring Centre (UNEP-WCMC) [90].

  - Comply with the Nagoya Protocol in Colombia and in the European Union by understanding its implementation mechanisms and by monitoring your value chain from source to market. Facilitate information to your potential (European) buyer.

  - Do not export prohibited substances, and respect the specific limits of constituents where applicable.

  - Make sure to provide the necessary technical information to your potential European buyer, and to facilitate any other documentation which will allow the importer and final buyer to comply with their legal obligations in the European Union. Provide a Technical Data Sheet (TDS), Certificate of Analysis (CoA) and a Safety Data Sheet (SDS), as well as other documentation required, complying with the necessary parameters.

83. https://www.cbi.eu/market-information/natural-ingredients-cosmetics
84. https://www.importpromotiondesk.com/en/media-center/market-information
85. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
86. https://eur-lex.europa.eu/homepage.html
87. https://trade.ec.europa.eu/access-to-markets/en/home
88. https://echa.europa.eu
89. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R1320
90. https://www.speciesplus.net

- When applicable, comply with the requirements of the Classification, Labelling and Packaging (CLP) regulation by classifying, packaging, labelling and transporting your products according to the Global Harmonized System (GHS) and by providing your buyer with a Safety Data Sheet (SDS).

- Carry out the necessary analysis of your vegetable oils and fats by an accredited laboratory.

- Collaborate with universities and other technical and research institutions for the elaboration of studies and documents that can evidence the efficacy, safety and performance of your ingredient(s), and organize this information into a dossier.

- Comply with requirements related to quality management and Environment, Safety and Health (EHS):

  - Implement processes of Hazard analysis and critical control points (HACCP) in the manufacturing plant, based on the Codex Alimentarius; the implementation of HACCP should be evidenced by a flow chart and possibly through a certificate.

    This is a minimum requirement for food ingredients (example: cooking / edible oil), but it is also commonly applied for cosmetics ingredients, especially when the product has microbiological parameters or specifications.

  - Consider the implementation of quality and safety management systems. For example, ISO 9001 can represent a competitive advantage for specific European buyers, particularly larger companies. The Guide on Good Manufacturing Practices (GMP), of the *European Federation for Cosmetic Ingredients* (EFfCI), according to ISO 221716 (Good Manufacturing Practices for Cosmetics) could also represent a competitive advantage for some buyers. It is recommended, however, that you first study your target market and buyer before engaging in auditing and de facto certification processes, which can be very costly.

  - Consider alliances with producers of organic raw material whose organic certification complies with the European Union's legislation, and who comply with Good Agricultural Practices.

This will help you mitigate the risks associated with cross-contamination from synthetic inputs and to enable you to target specific markets in Europe (i.e. the growing market for organic vegetable oils and fats).

- Explore other buyer requirements:
  - Identify other voluntary requirements according to your target market and buyer. Pay specific attention to sustainability requirements which may serve as a competitive advantage as a supplier. This can include certifications such as COSMOS[91] and NaTrue[92] or membership in sustainability platforms such as SEDEX[93].

91. https://www.cosmos-standard.org
92. https://www.natrue.org
93. https://www.sedex.com

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