EUROPEAN UNION REGULATION: NATURAL COLOURS

GOSP 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

GQSP GLOBAL QUALITY AND STANDARDS PROGRAMME

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1. Introduction

This technical sheet covers all products exported from Colombia to the European Union under HS code 32030010: Colouring matter of vegetable origin and preparations based thereon.

This document will allow Colombian exporters to identify and understand the main requirements to export natural colours 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 Natural Colours

Colombian exporters must meet a series of conditions before exporting natural colours. 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.

Natural colours whose end-use is animal or veterinary have to 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 ends, the certificate is issued by the ICA or Invima.

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

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

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.

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, including natural colours. An extract may be solid (e.g. crystals, resin, fine or

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

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 792/2012[9] 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 therein and 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.

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.

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 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.

For ingredients that are listed in the Annexes, buyers in the European Union willing to import the specific species (and derivatives) 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[13]. 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[14], 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.

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[15].

More information can be found on the page of the European Commission: *CITES: Permits, Certificates and Notifications*[16].

3.2 Nagoya Protocol

The implementation of the Nagoya Protocol on Access and Benefit Sharing (ABS) has important implications for natural ingredients, potentially including natural colours, 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.

13. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
14. https://cites.org/eng/parties/country-profiles/co/national-authorities
15. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
16. https://ec.europa.eu/environment/cites/info_permits_en.htm

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[17].

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).

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[18].

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).

17. https://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm
18. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

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)[19].

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[20] (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 natural colours. 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."[21]

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[22], 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[23]. 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[24].

A "substance" is defined in REACH[25] [26], as: a chemical element and its compounds in the natural state or obtained by any manufacturing

19. 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
20. https://op.europa.eu/en/publication-detail/-/publication/aefa4237-5477-11eb-b59f-01aa75ed71a1/language-en
21. 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
22. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
23. https://echa.europa.eu/regulations/reach/understanding-reach
24. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm
25. https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32006R1907&from=EN
26. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm

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[27].

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[28]:

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

European Union-based manufacturers or importers are the ones responsible for compliance with the REACH regulation. However, non-EU suppliers are expected to facilitate the necessary information and documentation which will enable EU importers to comply with their regulatory obligations. Alternatively, a non-EU supplier of natural colours can register ingredients themselves through an "only representative" established in the EU[29]. This can give them more flexibility as a supplier, as they are not dependent on an importer who is registered[30]. However, it is important to keep in mind that REACH costs and fees are very high, and the process requires extensive documentation[31].

The website of the European Chemicals Agency (ECHA) Understanding REACH[32] explains in detail the process of Identification, Registration, Evaluation and Authorization / Restriction of substances. In addition, the website *Information on Chemicals*[33] contains the full list of substances which are:

- Registered before the European Chemicals Agency (ECHA), for which all public data submitted to ECHA in REACH registration dossiers by substance manufacturers, importers, or their representatives, as laid out by the REACH Regulation, are available[34]. Examples of natural colours allowed in cosmetics, and which are listed under this category are:
  - Annatto: CAS number: 1393-63-1; EC number: 215-735-4[35]
  - *Curcuma longa*, ext.: CAS number: 84775-52-0; EC number: 283-882-1[36]

- Pre-registered. Pre-registration intentions for these substances were submitted to the European Chemicals Agency (ECHA) between 1 June and 1 December 2018. Full

27. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
28. https://echa.europa.eu/support/getting-started/am-i-exempt
29. https://echa.europa.eu/regulations/reach/registration
30. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/buyer-requirements
31. http://www.cirs-reach.com/REACH/REACH_Registration_Fees.html
32. https://echa.europa.eu/regulations/reach/understanding-reach
33. https://echa.europa.eu/information-on-chemicals
34. https://echa.europa.eu/information-on-chemicals/registered-substances
35. https://echa.europa.eu/substance-information/-/substanceinfo/100.014.305
36. https://echa.europa.eu/substance-information/-/substanceinfo/100.076.228

- registration is required for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer, unless they are exempted[37]. Examples of natural colours listed under this category, but not allowed in cosmetics as per Regulation (EC) No 338/97 are:
  - *Gardenia jasminoides*, ext.: CAS number: 92457-01-7; EC number: 296-280-9
  - *Roselle,* ext.: CAS number 84775-96-2; EC number: 283-920-7[38]

- Registered in quantities between 1 and 10 tonnes, predicted to meet criteria for category 1A or 1B for carcinogenicity, mutagenicity or reproductive toxicity (defined in Annex III of REACH)[39]. The fact that a substance is not in this list does not necessarily mean that the criteria for Annex III are not met[40]. If the substance is in the Annex III inventory, the company responsible for its registration will most likely need to submit the full Annex VII information[41]. Examples:
  - Annatto[42]: 1393-63-1; EC number: 215-735-4. Criteria:
    - suspected bioaccumulative, Suspected hazardous to the aquatic environment, Suspected persistent in the environment, Suspected toxic for reproduction.

4.2 Classification, Labelling and Packaging (CLP)

The Globally Harmonized System (GHS) of Classification and Labelling of Chemicals[43] is a system developed at the United Nations level to standardize and harmonize the management of chemicals globally. The United Nations Purple Book[44] 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

37. https://www.chemsafetypro.com/Topics/EU/REACH_Registration.html
38. https://echa.europa.eu/substance-information/-/substanceinfo/100.088.010
39. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&qid=1555077068696&from=EN#page=295
40. https://echa.europa.eu/information-on-chemicals/annex-iii-inventory
41. https://echa.europa.eu/support/registration/what-information-you-need/information-requirements-100-tn
42. https://echa.europa.eu/substance-information/-/substanceinfo/100.014.305
43. https://unece.org/about-ghs
44. https://unece.org/ghs-rev8-2019

Parliament and of the Council on classification, labelling and packaging of substances and mixtures[45]. **The regulation on Classification and Labelling of Chemicals (CLP) applies to natural colours for which hazard classification & labelling apply, regardless of the quantities traded. Therefore, substances traded in quantities of less than one tonne are not exempted.**

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[46].

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.
  - The dimensions of the label shall be as follows:

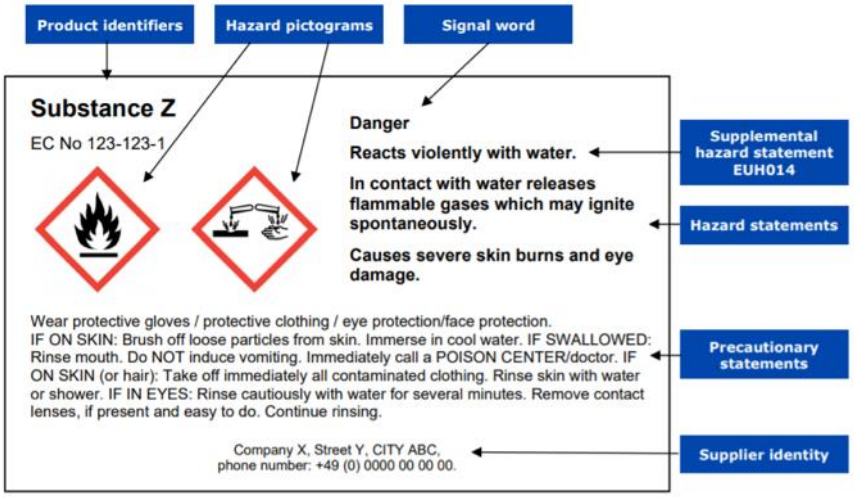
45. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272
46. https://echa.europa.eu/es/regulations/clp/labelling

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*[47], 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:

47. 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[48]. The Directive provides technical information for implementing European Union regulation on Classification, Labelling and Packaging. In addition, the database of the C&L Inventory[49] 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. Examples:

Hazard class and Category code(s) / Hazard statement code(s)	Labelling phrase	Signal words and Pictograms
Annatto: EC number 215-735-4[50]		
Skin Irrit. 2 / H315 Eye Irrit. 2 / H319	Causes skin irritation. Causes serious eye irritation.	Signal Word: Warning Pictograms:  Exclamation mark
Curcumins: EC number 207-280-5[51]		
There is no harmonized classification and there are no notified hazards by manufacturers, importers or downstream users for this substance.	Not applicable	Not applicable

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[52], which contains the necessary data that an SDS must have. This is a separate document that must be submitted to the buyer, and which is explained in more detail in section **7.2. Documentation requirements.**

48. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:225:0001:0333:EN:PDF
49. https://echa.europa.eu/es/information-on-chemicals/cl-inventory-database
50. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/6033
51. https://echa.europa.eu/substance-information/-/substanceinfo/100.006.619
52. https://echa.europa.eu/regulations/reach/legislation

Packaging

Article 35 of Regulation (EC) No 1272/2008 defines the packaging requirements of hazardous substances[53] applicable to some natural colours:

- The packaging is designed, constructed and fastened so that the contents cannot escape.
- The materials of the packaging and fastening are not damaged by the contents and are not liable to form hazardous compounds with the contents.
- The packaging and fastenings are strong and solid throughout to ensure that they will not loosen.
- Packaging fitted with replaceable fastening devices is properly designed to allow repeated refastening without the contents escaping.
- The packaging does not attract or arouse the curiosity of children or mislead the consumer when supplied to the general public.
- The packaging does not have a similar presentation or a design used for foodstuff or animal feed stuff or medicinal or cosmetic products which would mislead the consumers.

For recommendations of specific packaging materials which will allow suppliers of natural colours to comply with these requirements, consult section **7.3. Packaging and Transport.**

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[54]. 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[55].

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

53. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65
54. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
55. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D0674

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.[56]

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[57]
- Cosmetics Directive 76/768/EEC (cosmetics directive), as amended[58]
- 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)[59]

The Cosmetic Ingredient (CosIng) database[60] 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)[61]. 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.[62]

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

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

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. Because natural colours that are allowed in cosmetics are listed under Annex IV - Allowed Colorants, the substances that are not in this annex are automatically prohibited to be used as colorants.

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[63].

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. Natural colours are specifically treated under Annex IV - Allowed Colorants, which includes the specific purity criteria under which they're authorized for use in cosmetics.

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[64].

5.3 Cosmetic Products Regulation, Annex IV – Allowed Colorants

Annex IV of Regulation (EC) No. 1223/2009, lists the substances which are allowed for use as colourants in cosmetic products. Among the 300+ substances listed[65] there are very few natural / botanical ingredients; for example: curcumin (*Curcuma longa)*[66], annatto[67] (*Bixa orellana*), paprika extract (capsanthin[68] and capsorubin[69]). Each (natural) colour allowed for use in cosmetics has specific purity criteria, which are referenced in the European Union's food legislation, namely the Commission Directive 2008/128/EC, laying down specific purity criteria concerning colours for use in foodstuffs[70] - therefore identified by E-numbers. For example:

63. https://www.echa.europa.eu/cosmetics-prohibited-substances
64. https://echa.europa.eu/cosmetics-restricted-substances
65. https://echa.europa.eu/cosmetics-colorant
66. https://echa.europa.eu/substance-information/-/substanceinfo/100.006.619
67. https://echa.europa.eu/substance-information/-/substanceinfo/100.014.305
68. https://echa.europa.eu/substance-information/-/substanceinfo/100.006.696
69. https://echa.europa.eu/substance-information/-/substanceinfo/100.006.752
70. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0128&from=FI

- Curcumin (E100)
  - Solvent residues: Ethylacetate, Acetone, Methanol, Ethanol, Hexane, n-butanol (Not more than 50 mg/kg, singly or in combination); Dichloromethane (not more than 10 mg/kg)
  - Arsenic (not more than 10 mg/kg)
  - Lead (not more than 10 mg/kg)
  - Mercury (not more than 1 mg/kg)
  - Cadmium (not more than 1 mg/kg)
  - Heavy metals, as Pb (not more than 40 mg/kg)

- Annatto (Bixin, Norbixin) (E160b)
  - Solvent residues: Acetone, Methanol, Hexane (Not more than 50 mg/kg, singly or in combination); Dichloromethane (not more than 10 mg/kg)
  - Arsenic (not more than 3 mg/kg)
  - Lead (not more than 10 mg/kg)
  - Mercury (not more than 1 mg/kg)
  - Cadmium (not more than 1 mg/kg)
  - Heavy metals, as Pb (not more than 40 mg/kg)

The complete list of colours allowed in cosmetic products (and updates) can be found on Annex IV on the platform of the *European Chemicals Agency: Cosmetic Products Regulation, Annex IV -Allowed Colorants*[71].

5.4 Cosmetic Products Regulation, Annex V – Allowed Preservatives

Not relevant for natural colours.

5.5 Cosmetic Products Regulation, Annex VI – Allowed UV Filters

Not relevant for natural colours.

6. Other standards

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[72]. The complete list of COSMOS-certified cosmetic products can be found in the database: *COSMOS-certified cosmetic products*[73].

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[74]. The standards include elements such as: prohibition

71. https://echa.europa.eu/cosmetics-colorant
72. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
73. http://cosmos-standard-rm.org/data/indexcp.php
74. https://natrue.org/uploads/2019/05/ES-NATRUE-Label_Requirements_V3.8-1.pdf

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[75], compiled by Andrew Jones (Fair Venture Consulting)[76] and ProFound – Advisers In Development[77] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[78] has a few examples of questions from supplier questionnaires that are implemented by European buyers. **In this workbook, natural colours are included in the category of extracts.**

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 natural colours 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 Integrated Crop Management (ICM).

75. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
76. https://www.fairventure.com
77. https://thisisprofound.com
78. https://www.cbi.eu

There is also an interesting growth among European buyers in the demand for organic-certified natural colours, 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 natural colours 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: natural food colours), 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 natural colours 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[79]. However, **remember that only the natural colours that are listed in Annex IV of Regulation (EC) No. 1223/2009, are allowed for use as colourants in cosmetic products.**

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[80]**, compiled by Andrew Jones (Fair Venture Consulting)[81] and ProFound – Advisers In Development[82] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[83]. This guide explains the different elements which a dossier should contain. In this workbook, natural colours are included in the category of extracts.

The 3 essential documents required by buyers of natural colours in the European Union are[84]:

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

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[85]** . In general, the content of these 3 documents for extracts, including natural colours, consist of the following elements:

Technical Data Sheets (TDS)	Certificate of Analysis (CoA)	Safety Data Sheets (SDS)
• Product name and Description • Key components • INCI name • CAS number • EINECS number • Simplified description of manufacturing process • % Impurities • Heavy metal analysis • Particle size • Solubility in water, oil, alcohol • Microbial analysis	• Product name • Description • Key components • INCI name • Key components • CAS number • EINECS number • % impurities • Heavy metal analyses • Particle size • Solubility in water, oil, alcohol • Microbial analysis	• Product name • Description • INCI name • CAS number • EINECS number • Toxic components (names, concentration) when applicable • Published studies, reports, references on safety and efficacy • Toxicological tests • Local toxicity

79. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
80. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
81. https://www.fairventure.com
82. https://thisisprofound.com
83. https://www.cbi.eu
84. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient#setting-up-your-dossier
85. 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)
• Colour, odour • Moisture • Preservatives • Toxic components (names, concentration) when applicable • Pesticide residues • Shelf life under stated conditions • Type of packaging • Recommended storage • Access permits (ABS) and other certifications	• Colour, odour • Moisture • Preservatives • Toxic components (names, concentration) when applicable • Pesticide residues (periodic, not for each batch)	• Primary skin irritation • Ocular irritation • Allergenicity • Sensitisation • Systemic toxicity • Mutagenesis: Ames test • Acute toxicity • Efficacy studies (own, published) • Efficacy data summary • Summary of safety data • Recommended conditions of use: product type, part of body, 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)[86].**

Other documentation which may be required by EU buyers of natural colours 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[87].
- *Allergen declaration*
- *CMR declaration* (non-mutagenic, carcinogenic, toxic)
- *BSE/TSE declaration*
- *Heavy metals declaration*
- *Non-Nanoparticles declaration*

7.3 Packaging and Transport

The packaging of specific natural colours will vary according to their presentation (liquid, powder, etc.):

- Solid extracts (powder) in bulk are normally packed and transported in 25 kg paper bags, although some European buyers prefer polypropylene bags for the best maintenance of product quality. Lesser known extracts are sometimes packed in smaller volumes, example: 1-5 kg bags.
- Liquid natural colours are commonly packaged and transported in drums of High density

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

polyethylene (HDPE), stainless steel / aluminum drums or Intermediate Bulk Containers (IBC) with inner liner that prevent product oxidation. The specific preferences will depend on each buyer. Additionally, some cosmetic ingredient buyers will require that packages be approved as food-grade.

Most natural colours currently approved in cosmetics are not considered to be hazardous substances, and therefore do not contain a UN number; as such, their packaging and transport are not specifically regulated.

To obtain specific information on UN-approved packaging and transport of these substances refer to the UN Recommendations on the Transport of Dangerous Goods[88]

8. Final recommendations

- Read more about the regulatory framework, buyer requirements and market developments for natural colours in the European Union:
  - Centre for the Promotion of Imports from Developing Countries (CBI): Market Information on Natural Ingredients for Cosmetics[89]
  - Import Promotion Desk (IPD): Market Information on Natural Colourants[90]
- Consult official data sources in the European Union to learn more about the regulatory requirements:
  - European Commission[91]
  - EUR-LEX[92]
  - Access2Markets[93]
  - The European Chemicals Agency (ECHA)[94]
- Consult the website of the Natural Food Colours Association (NATCOL)[95] to follow industry-wide discussions and regulatory updates. Even though the association focuses on the food industry, natural colours used in cosmetics are also used in food.
- Comply with the minimum legislative requirements for natural colours 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. However, note that none of the natural colours currently allowed for use in cosmetics under Regulation (EC) No 338/97 is listed under these Annexes. Follow any future updates to the species listed in these Annexes by directly accessing Regulation (EU) No. 1320 / 2014[96] and the

88. https://unece.org/rev-21-2019
89. https://www.cbi.eu/market-information/natural-ingredients-cosmetics
90. https://www.importpromotiondesk.com/fileadmin/user_upload/Publikationen/factsheet/zutaten/Natural_Colourants.pdf
91. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
92. https://eur-lex.europa.eu/homepage.html
93. https://trade.ec.europa.eu/access-to-markets/en/home
94. https://echa.europa.eu
95. https://natcol.org
96. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R1320

Species+ website of the United Nations Environment Programme - World Conservation Monitoring Centre (UNEP-WCMC)[97].

- 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 purity criteria where applicable. Alternatively, explore opportunities within other market segments such as food. The range of natural colours allowed in foodstuffs and the volumes used in the food industry are normally greater than in the cosmetics industry.
- 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.
- 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).
- Carry out the necessary analysis of your natural colours by an accredited laboratory, paying special attention in complying with the purity criteria as established by COMMISSION DIRECTIVE 2008/128/EC.
- 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.

- For exporters of natural colours that fall under REACH regulation:
  - Prior to engaging in the registration process, verify whether your potential European buyer demands more than one tonne of your product per year. Ingredients traded in less than one tonne per product, per company, are exempted from the REACH regulation.
  - If your potential European buyer requires you to present a REACH Certificate of Compliance, search for an authorized and qualified

97. https://www.speciesplus.net

EU-based "only representative"[98] to fulfill these duties.

- Seek collaboration with other Colombian companies handling the same ingredient and engage in a collective process for its registration and authorization required by the REACH regulation. Not only can this lower the actual costs, but also facilitate processes such as the compilation of the necessary information for technical and scientific dossiers.

- 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: natural food colours), 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 natural colours).

- 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[99] and NaTrue[100] or membership in sustainability platforms such as SEDEX[101].

98. https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/Only+Representative+of+non-EU+manufacturer
99. https://www.cosmos-standard.org
100. https://www.natrue.org
101. https://www.sedex.com

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