

**OVERVIEW REQUIREMENTS FOR  
FOOD CONTACT MATERIALS  
AND  
HERBALIFE AOP's**

## GENERAL INFORMATION

Homepage for summaries of EU legislation: <http://eur-lex.europa.eu/browse/summaries.html>

Homepage EU Food Safety: [http://ec.europa.eu/food/safety/index\\_en.htm](http://ec.europa.eu/food/safety/index_en.htm)

Homepage EU Consolidated legislation: <http://eur-lex.europa.eu/collection/eu-law/consleg.html>

Homepage EU product safety:

[http://ec.europa.eu/consumers/consumers\\_safety/safety\\_products/index\\_en.htm](http://ec.europa.eu/consumers/consumers_safety/safety_products/index_en.htm)

## OVERVIEW PRODUCT GROUPS

Textile

Toys

Mineral Waters

Food Contact Materials, plastics

Food Contact Materials, ceramics

Food Contact Materials, polyamide and melamine plastic kitchenware from PR of China and Hong Kong

Food Contact materials

Cosmetics

Medical Devices

General [other products]

**PRODUCT GROUP:**  
**TEXTILE**

**DEFINITION**

Textile product means any raw, semi-worked, worked, semi-manufactured, manufactured, semi-made-up or made-up product which is exclusively composed of textile fibres, regardless of the mixing or assembly process employed.

**LEGISLATION**

Regulation EU 1007/2011 as amended

**LINK TO TEXT OF LEGISLATION**

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431076345638&uri=CELEX:02011R1007-20130701>

**REQUIRED DOCUMENTS**

Declaration of Compliance

**PRODUCT GROUP:**  
**TOYS**

**DEFINITION**

Products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

Excluded are products mentioned in Annex I of the legislation

**LEGISLATION**

Directive 2009/48/EC as amended

**LINK TO TEXT OF LEGISLATION**

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431076390317&uri=CELEX:02009L0048-20140721>

**REQUIRED DOCUMENTS**

EC declaration of conformity as per article 15 and Annex III of the regulation

If available test report

**PRODUCT GROUP:**  
**MINERAL WATERS**

**DEFINITION**

Waters extracted from the ground of a Member State and recognized by the responsible authority of that Member State as natural mineral waters satisfying the provisions of Annex I, Section I of Directive 2009/54/EC.

Waters extracted from the ground of a third country, imported into the Community and recognized as natural mineral waters by the responsible authority of a Member State.

**LEGISLATION**

Directive 2009/54/EC on the exploitation and marketing of natural mineral waters as amended  
Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters as amended

Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters as amended

List of natural mineral waters recognized by Member States, last update 13 April 2015

**LINK TO TEXT OF LEGISLATION**

2009/54/EC: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009L0054>

2003/40/EC: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32003L0040>

EU 115/2010: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:037:0013:0015:EN:PDF>

List of recognized natural mineral waters:

[http://ec.europa.eu/food/food/labellingnutrition/water/docs/mw\\_eulist\\_en.pdf](http://ec.europa.eu/food/food/labellingnutrition/water/docs/mw_eulist_en.pdf)

General information with links to legislation regarding mineral waters

[http://ec.europa.eu/food/food/labellingnutrition/water/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/water/index_en.htm)

**REQUIRED DOCUMENTS**

Declaration of Compliance

**OTHERS**

Labelling includes mandatory information:

- the statement of analytical composition;
- the name of the spring and the place of exploitation;
- information on any treatments.

**PRODUCT GROUP:**  
**FOOD CONTACT MATERIAL [FCM], PLASTICS**

**DEFINITION**

Materials and articles which are placed on the EU market and fall under the following categories:

- materials and articles and parts thereof consisting exclusively of plastics;
- plastic multi-layer materials and articles held together by adhesives or by other means;
- materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
- plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
- plastic layers in multi-material multi-layer materials and articles.

**LEGISLATION**

EU 10/2011 on plastic materials and articles intended to come into contact with food as amended

**LINK TO TEXT OF LEGISLATION**

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431076263982&uri=CELEX:02011R0010-20150226>

General information with links to legislation and documents:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/10-2011\\_plastic\\_guidance\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/10-2011_plastic_guidance_en.pdf)

Guidance document for product testing

[http://publications.jrc.ec.europa.eu/repository/bitstream/JRC51601/guidelines%20test%20conditions\\_final\\_ed2009.pdf](http://publications.jrc.ec.europa.eu/repository/bitstream/JRC51601/guidelines%20test%20conditions_final_ed2009.pdf)

<http://www.plasticseurope.org/documents/document/20111208094327->

[foodcontact\\_pim\\_explanatory\\_document\\_7\\_december\\_2011.pdf](http://www.plasticseurope.org/documents/document/20111208094327-foodcontact_pim_explanatory_document_7_december_2011.pdf)

**REQUIRED DOCUMENTS**

Declaration of Compliance as per EU10/2011 annex IV as amended

**PRODUCT GROUP:**  
**FOOD CONTACT MATERIAL [FCM], CERAMICS**

**DEFINITION**

Ceramic articles means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enameled and/or decorated.

**LEGISLATION**

Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs as amended

**LINK TO TEXT OF LEGISLATION**

84/500/EEC:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431076097729&uri=CELEX:01984L0500-20050520>

General information with links to legislation and documents:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

**REQUIRED DOCUMENTS**

Declaration of Compliance as per Directive 84/500/EEC annex III



**PRODUCT GROUP:**  
**FOOD CONTACT MATERIAL [FCM], POLYAMIDE AND MELAMINE PLASTIC KITCHENWARE FROM THE  
PEOPLE REPUBLIC OF CHINA AND HONG KONG SPECIAL ADMINISTRATIVE REGION, CHINA**

**DEFINITION**

Plastic kitchenware means plastic materials as described in paragraphs 1 and 2 of Article 1 of Directive 2002/72/EC and falling within CN code ex 3924 10 00

**LEGISLATION**

Regulation EU 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China as amended

**LINK TO TEXT OF LEGISLATION**

EU 284/2011 <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0284>

General information with links to legislation and documents:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

**REQUIRED DOCUMENTS**

Declaration as per the Annex of Regulation EU 284/2011  
Laboratory report as per Article 3 of Regulation EU 284/2011

**OTHERS**

Importers or their representatives shall notify the competent authority at the first point of introduction at least two working days in advance of the estimated date and time of physical arrival of consignments originating in or consigned from China and Hong Kong.

**PRODUCT GROUP:**  
**FOOD CONTACT MATERIALS [FCM]**

**DEFINITION**

Materials and articles, including active and intelligent food contact materials and articles, which in their finished state:

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

**LEGISLATION**

Regulation EU 1935/2004 on materials and articles intended to come into contact with food as amended

Regulation EU 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food as amended [BADGE, BFDGE and NOGE]

**LINK TO TEXT OF LEGISLATION**

EU 1935/2004

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431076580221&uri=CELEX:02004R1935-20090807>

EU1895/2005:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32005R1895>

General information with links to legislation and documents:

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/practical\\_guide\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/practical_guide_en.pdf)

<https://ec.europa.eu/jrc/en/eurl/food-contact-materials>

**REQUIRED DOCUMENTS**

Declaration of Compliance as per Article 16 of Regulation EU 1935/2004.

Declaration of Compliance should include a declaration as per article 5 of Regulation EU 1895/2005

**PRODUCT GROUP:**

**COSMETICS**

**DEFINITION**

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

**LEGISLATION**

Regulation [EC] 1223/2009 on cosmetic products

**LINK TO TEXT OF LEGISLATION**

Regulation [EC] 1223/2009 – consolidated

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431075830879&uri=CELEX:02009R1223-20150416>

**REQUIRED DOCUMENTS**

Product specification

Certificate of Analysis [including microbiological test results]

**OTHERS**

Glossary and acronyms related to cosmetics legislation:

[http://ec.europa.eu/growth/sectors/cosmetics/docs/glossary\\_and\\_acronyms\\_related\\_to\\_cosmetics\\_legislation\\_en.pdf](http://ec.europa.eu/growth/sectors/cosmetics/docs/glossary_and_acronyms_related_to_cosmetics_legislation_en.pdf)

**PRODUCT GROUP:**  
**MEDICAL DEVICES**

**DEFINITION**

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception.

**LEGISLATION**

Directive 93/42/EEC concerning medical devices as amended

**LINK TO TEXT OF LEGISLATION**

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431085745028&uri=CELEX:01993L0042-20071011>

**REQUIRED DOCUMENTS**

Declaration of Conformity as per annexes of directive 93/42/EEC as amended

**PRODUCT GROUP:**  
**GENERAL [PRODUCTS NOT BELONGING TO A SPECIFIC GROUP]**

**DEFINITION**

N.A.

**LEGISLATION**

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended

**LINK TO TEXT OF LEGISLATION**

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431694813390&uri=CELEX:02006R1907-20150323>

Other information:

<http://echa.europa.eu/regulations/reach>

**REQUIRED DOCUMENTS**

Declaration of Compliance

**OTHERS**

In case of products in direct and prolonged contact with the skin [fancy jewelry, watches etc], the Declaration should also refer that the product comply with European Regulation [EC] No. 1907/2006, annex XVII. No. 27 as amended [nickel migration].

If available a test report to demonstrate compliance with the nickel migration requirement.