



**CARIBBEAN EXPORT DEVELOPMENT AGENCY/ONSITE  
CARIBBEAN 2 PROJECT**

Guidelines for technical  
regulations and standards in  
the European Union Market  
for artisanal products  
**REPORT**

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## About this report

This report, prepared at the request of the Caribbean Export Development Agency in Barbados, presents guidelines for technical regulations and standards which are likely to be applied in the European Union (EU) market to the assessment of compliance of artisanal products. It is prepared for Caribbean designers and artisans as part of the Onsite Caribbean 2 project which will develop unique Caribbean products using a merger of Caribbean-based design talent interfacing with artisanal producers. The team envisions that the resulting products will be part of an extra-regional showcase at the Maison & Objet trade show in France in January 2010.

The contents of the report are based on information on legislative and non-legislative requirements, obtained from the website ([www.cbi.eu](http://www.cbi.eu)) of the Centre for Promotion of Imports from Developing Countries (CBI). To obtain similar information on other products, go to 'Search CBI database' at <http://www.cbi.eu/marketinfo>, select your market sector and the EU in the category search, click on the search button and click on market access requirements. Registration on the site may be a requirement to access information. While the information contained in this report is believed to be accurate at the time of writing based on the research efforts involved in its preparation, the report is not intended as a substitute for legal or marketing advice and no liability will be assumed by the Agency or its authors arising from the use or interpretation of the information contained herein.

## About market access requirements

Producers in developing countries preparing to access EU markets should familiarize themselves with market access requirements of potential or existing trading partners and the EU governments. The EU currently comprises 27 Member States and consequently market requirements may vary according to individual Member States and/or specific marketing channels (i.e. wholesale, retail, hypermarket, etc.) They may take the form of legislation affecting labels, codes and management systems. In general however, there is a move towards harmonization of standards and market requirements are based on logical, but sometimes highly technical, environmental, consumer health and safety and social concerns. Responsibility for compliance with EU legislation must be assumed by exporters and their EU based trading partners and small exporters should ensure that they use their relationships with buyers as a resource to keep abreast of changes and new legislation and pinpoint exact product modifications required to improve market suitability.

## EU legislation for packaging and packaging waste

Product Category: ALL

Product Standard/ Technical Regulation: EU Directive 94/62/EC

**Rationale/ Associated Issues** In order to reduce the impact of packaging on the environment and harmonize the different forms of legislation on packaging and packaging waste in EU countries, the EU has issued Directive 94/62/EC, which regulates minimum requirements for the management of packaging and packaging waste. These measures aim at preventing the production of packaging waste, and in addition at reusing packaging, at recycling and other forms of recovering packaging waste and as such to reduce the final disposal of such waste. As of August 1, 2001, these minimum requirements will require a recovery quota of 50-65 percent for packaging materials brought into the EU and will regulate the presence of four heavy metals (mercury, lead, cadmium and hexavalent chromium) in packaging and labelling. EU countries have a certain freedom in how to comply with the recovery rate but at least 25-45 percent of the material brought into the EU must be recycled, with a minimum of 15 percent for each material. The maximum available sum of concentrations of lead, mercury and hexavalent chromium in packaging is 100 parts per million. These requirements were approved by the EU countries in 1996 and are now in force in most of them. Each country reserves the right to apply additional requirements, as long as these do not hamper trade between countries.

**Scope** Directive 94/62/EC covers: **Packaging:** All products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. 'Non-returnable' items used for the same purposes are also considered to be packaging. Annex I to the Directive lists items that are illustrative examples of the application of these criteria. According to that list, tea bags and wax layers around cheese, so called 'food contact materials', are considered non-packaging materials, while the film overwrap around a CD case, paper or plastic carrier bags, or labels hung directly on or attached to a product are considered packaging.

**Packaging waste:** The Directive refers to the definition of 'waste' in Directive 2006/12/EC as any substance or object which the holder disposes or at some point will or has to dispose. For example, contaminated or soiled materials, materials whose date for appropriate use has expired, spilled, or misshaped materials, adulterated materials, materials of which the use of has been banned by the EU, etc.

## How to Comply

Compliance with EU requirements can be shown by using harmonized standards. The European standardization body (CEN) has released six European standards that support the essential requirements of Directive 94/62/EC on packaging and packaging waste.

Standard No.	Title	Function
EN 13427:2004	Packaging – Requirements for the use of European Standards in the field of packaging and packaging waste	Guidelines
EN 13428:2004	Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction	Optimised use of packaging
EN 13429:2004	Packaging – Reuse	Reusable packaging
EN 13430:2004	Packaging – Requirements for packaging recoverable by material recycling	Material recoverable packaging
EN 13431:2004	Packaging – Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value	Energy recoverable packaging
EN 13432:2000	Packaging - Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging	Compostable packaging

The Green Dot (German: Der Grüne Punkt)

The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods. Although it is no legal EU requirements, many products marketed in the EU present the symbol in their packaging. In Germany the symbol was obligatory until 1 January 2009. However, the symbol is required in packaging and packaged products marketed on the French, Spanish, Bulgaria and Portuguese market. As a result, packaging to be marketed in several Member States usually bears the Green Dot symbol.

### Implications for Caribbean artisanal producers

All exporters of goods to EU markets are required to comply with the requirements on packaging recovery, heavy metal detection and labelling in order to gain market entry. EU importers (or resellers and distributors) may also ask their suppliers to comply with additional requirements on packaging reduction and/or prefer recycled packaging materials. These requirements are sometimes forced by national economic instruments established by Member States (e.g. UK and the Netherlands), such as a packaging tax. Each company is also part of a supply chain and therefore an EU buyer might set requirements related to his supply chain management. Caribbean exporters desirous of entering the market must be aware of these requirements and ensure that they engage potential buyers in discussions about compliance with these regulations.

### Further information

- . • Centre for Promotion of Imports from Developing Countries [www.cbi.eu](http://www.cbi.eu)
- . • International Trade Centre (ITC) <http://www.intracen.org/ep/packaging/packit.htm>
- . • UK The Industry Council for Packaging and the Environment <http://www.incpen.org>

<b>EU legislation on wooden packaging material</b>
<b>Product Category:</b> ALL
<b>Product Standard/ Technical Regulation:</b> Directives 2004/102/EC, 2006/14/EC, 2008/109/EC, 2000/29/EC
<p><b>Rationale/ Associated Issues</b> On March 1st, 2005, the EU introduced a set of new requirements for wood packaging materials. The rules are aimed at preventing plant viruses and the like from entering Europe. The EU has laid down phyto-sanitary (plant health) requirements in order to prevent the introduction of organisms harmful to plants and plant products, and their spread within the EU. Harmful organisms are any species, strain or biotype of plant, animal or pathogenic agent that is injurious to plants or plants products. Examples of organisms harmful to plants and plant products are certain insects, mites and nematodes, bacteria, fungi and viruses and virus-like organisms. Wood packaging material (e.g. packing cases, boxes, crates, drums, pallets, box pallets) or dunnage (wood used to wedge and support non-wood cargo) are considered pathways for the introduction and spread of pests. Wood packaging material is considered a plant product and is among those products that can carry harmful organisms such as insects or viruses. The EU Directive applies to all wood packaging materials imported into the EU. One of the main requirements is that wood packaging material has to go through heat treatment that involves a minimum wood core temperature of 56 degrees Celsius for a minimum of 30 minutes (heat treatment or HT). Alternatively, it may be fumigated with methyl bromide. Moreover, the treated wood must bear a mark with the two-letter ISO country code, a code identifying the producer and a code identifying the approved measure applied to the wood packaging material.</p>
<p><b>Scope</b> Directive 2000/29/EC covers: 1. <b>Wood packaging materials (WPM):</b> Wood or wood products (excluding paper products) used in supporting, protecting or carrying a commodity, e.g. in the form of packing cases, boxes, crates, drums and similar packing, pallets, box pallets and other load boards, pallet collars. 2. <b>Dunnage:</b> Wood used to wedge or support non-wood commodity but which does not remain associated with the commodity.</p>

From the scope of the Directive are exempted:

- raw wood of 6 mm thickness or less, and
  - processed wood produced by glue, heat and pressure, or a combination thereof.
- Directive 2004/102/EC, Directive 2006/14/EC and Directive 2008/109/EC, which amend Directive 2000/29/EC, introduced requirements for the import of wood packaging material and dunnage that is used for export of goods to the EU. The Directives set special market access requirements for wood packaging material (WPM) and wood used to wedge or support non-wood cargo (dunnage). WPM and dunnage must be treated and marked according to the International Standard for Phytosanitary Measure (ISPM) No. 15 established by the International Plant Protection Convention (IPPC).

## International Plant Protection Convention (IPPC)

The IPPC is an international treaty to secure action to prevent the spread and introduction of pests and plant products, and to promote appropriate measures for their control. It is governed by the Interim Commission on Phytosanitary Measure (ICPM) which adopts ISPMs.

## International Standard for Phytosanitary Measure (ISPM)

ISPMs are prepared by the Secretariat of the IPPC as part of the Food and Agriculture Organisation (FAO) of the United Nations' global programme of policy and technical assistance in plant quarantine. The standard *ISPM 15: Guidelines for regulating wood packaging* is available to all FAO members and other interested parties.

## Reduction of methyl bromides

Methyl bromide is listed as an ozone-depleting substance subject to phase-out under the Montreal Protocol. IPPC is currently working on a standard on how to replace or reduce the use of methyl bromides as a phytosanitary measure. The following examples of phytosanitary measures may be implemented to replace or reduce methyl bromide as a treatment in wood packaging:

- .       • use of other chemicals (e.g. sulfuryl fluoride, methyl iodide)
- .       • application of physical treatments (e.g. heating, cooling, irradiation)
- .       • immediate commodity processing (e.g. grain being milled into flour on arrival)
- .       •       improvement of treatment facilities in order to increase exposure time with a reduction of dosage
- .       •       use of higher temperatures when fumigating

                  methods of production (e.g. soil-free growing media, tissue culture, sterile culture)

## How to Comply

### Debarking (applicable as of 1 July 2009)

Wood Packaging Material (WPM) must be free from bark with the exception of any number of individual pieces of bark if they are either less than 3 cm in width (regardless of the length) or, if greater than 3 cm in width, of not more than 50 cm<sup>2</sup> in area.

### Treatment

WPM (including dunnage) should be treated with an approved method as specified in Annex I of ISPM 15, which can be:

1.       1.       Heat Treatment (HT) that achieves a minimum wood core temperature of 56°C for a minimum of 30 minutes. Kiln-drying (KD), chemical pressure impregnation (CPI), or other treatments may be considered HT treatments as long as they meet the HT specifications.
2.       2.       Fumigation with Methyl Bromide (MB) in alignment with ISPM 15 requirements. In any case, minimum temperature should not be less than 10°C and the minimum exposure time should be 24 hours. It should be noted that Methyl bromide is listed as an ozone-depleting substance subject to phase-out under the Montreal Protocol. IPPC is currently working on a standard on how to replace or reduce the use of methyl bromides as a phytosanitary measure.

### Marking

WPM (including dunnage) must display at minimum:



1. 1. the ISPM 15 logo
2. 2. the two letter country code followed by a unique number assigned by the National Plant Protection Organisation (NPPO) to the producer of the wood packaging material that is responsible for ensuring appropriate wood is used and properly marked the IPPC abbreviation for the treatment used (e.g. HT, MB).

## Implications for Caribbean artisanal producers

Caribbean producers must comply with this statute on wooden packaging and dunnage. Indications at this point are that the regulations apply specifically to wooden packaging and not processed products of wood and plant material. However, it is clear that a similar case for phytosanitary requirements could be made by any EU importing market. National contact points for International Phytosanitary Portal (IPP) are indicated below. Caribbean Export is in the process of clarifying the specific phytosanitary requirements that will apply to artisanal products entering France in 2010. For other shipments, producers of basketry, wood products and products of unprocessed plant fibre and plant material are advised to consult their national contact points for further clarification on the need for pre-shipment treatments.

## Further information

Nearly every country has a National Plant Protection Organisation (NPPO) that is responsible for its national phytosanitary schemes, including the ISPM 15 standard. Exporters of regular shipments to Europe should contact the national plant protection organization (NPPO) for questions about the procedure for treatment and marking of WPM according to IPSP 15 and to determine how to go about obtaining the necessary certifying mark to accompany wooden packaging where this is required. Go to the official site of the International Plant Protection Convention (<http://www.ippc.int/>) to find more information (click on “national”).

## EU legislation: Liability for defective products

**Product Category:** ALL

**Product Standard/ Technical Regulation:** Directive 85/374/EEC

**Rationale/ Associated Issues** Directive 85/374/EEC on liability for defective products covers all products for which there is no specific legislation. These can include a range of products from cars to cots, from tyres to toys and from food to pharmaceuticals. The aim of Directive 85/374/EEC is to protect the well-being and property of the consumer. Moreover, it aims to find the optimum system for compensating the victims of damage caused by defective products and improving the quality of products, without dampening industry's capacity for innovation.

**Scope** The Directive applies to products not covered by specific legislation on liability. The Directive defines products as “movables which have been industrially produced, whether or not incorporated into another movable or into an immovable”. The liability of producers only applies to death or physical injury and damage to goods for private use. A producer is liable if a causal relationship can be established between a defect in his product and damage. Producer is defined in the widest possible language and although the European importer is responsible for the products he puts on the market, he may pass on a claim to the manufacturer/exporter, if, for example, it appears that the product was not produced in conformity with the specifications agreed upon. The Directive is intended to be invoked when a product is not as safe as the general public is entitled to expect. Factors to be taken into account include: • the presentation of the product • the use to which it could reasonably be put • the time when the product was put into circulation Directive 85/374/EC states that, where two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the right of covering a bad debt. The Directive allows each Member State to set a limit for a producer's total liability for damage resulting from death or personal injury caused by identical items with the same defect. This limit may not be lower than 70 million Euro. In order to prove that a product was defect, the injured person must prove: • the actual damage • the defect in the product • the causal relationship between damage and defect

**How to Comply** In order to minimize the risk, the following preventive measures are advised: • Compliance with the legislation and international product standards • An effective quality-management system • Systematic assessment of suppliers • Procedures for product recall, registration and evaluation of customer complaints • Assessment of foreseeable misuse of products, shelf life and storage • Carefully formulated labels, instructions for use and disclaimers

**Implications for Caribbean artisanal producers** The legislation applies primarily to items with mechanical and moving parts but could be interpreted to apply to any product. However, there are implications for artisanal producers, for example of wooden toys or furniture and screens requiring a structural component to their designs. There is a particular scrutiny in the EU about the safety of products for children's use. Producers should therefore investigate with the assistance of their national Bureau of Standards or standards contact point, the relevant international product standards, in order to avoid potential complications.

**Further information** See Directive 85/374/EEC: <http://www.dehp-facts.com/upload/documents/webpage/document42.pdf>

<b>EU legislation: General product safety</b>
<b>Product Category: ALL</b>
<b>Product Standard/ Technical Regulation: Directive 2001/95/EC</b>
<p><b>Rationale/ Associated Issues</b> The General Product Safety Directive (GPSD) (Directive 2001/95/EC) aims to protect EU consumers' health and safety and sets basic rules for safe products in the EU. According to the Directive, producers have an obligation to place only safe products on the EU market and it is prohibited to place products that pose a risk to consumers' health, caused by dangerous substances or by unsafe construction in the market. Only 'safe products' may be sold. This general Directive applies to all non-food products marketed in the EU. However, where products are subject to specific safety requirements imposed by other EU legislation (e.g. toys, chemicals, cosmetics, machinery), the General Product Safety Directive <b>applies only to the aspects and risks not covered by the specific legislation</b>. Products that do not comply with the general safety requirement will be refused entry to the EU market.</p>
<p><b>Scope</b> The GPSD applies to all products on the consumer market or products likely to be used by consumers (including products that are used to provide services to consumers), whether used, new or reconditioned. Under Directive 2001/95/EC, the Member States' national inspection authorities established a <i>European network</i> called RAPEX, in order to facilitate the quick exchange of information on potential threats. According to the 2008 annual report, the EU alerted on non-compliance of consumer products (1,866 notifications in total) mainly belonging to the following product categories: toys (32%); electrical appliances (11%); motor vehicles (10%); clothing, textiles and fashion items (9%); childcare articles and children's equipment (6%); and other (32%). The most common risks observed were: injuries (20%); chemical risks (19%); choking (16%); electrical shock (15%); fire (10%); and other (20%).</p>
<p><b>How to Comply</b> The Directive indicates that a product is considered safe where: • It complies with the EU requirements for the safety of the product in question as expressed in general legislation and specific product standards. • In the absence of specific product provisions on EU level, the product must comply with the specific national requirements of the Member State in which it is being marketed or sold, or with the voluntary national standards which transpose the European standards or legislation.</p>

- If these are absent, then the following compliance issues are relevant: codes of good practice as regards health and safety; current state of the art; consumers' safety expectations.

## Implications for Caribbean artisanal producers:

All products placed on the EU market must in every instance comply with the general safety requirement. Depending on who places the product on the EU market, the responsibility for compliance could fall with the European producer, importer or retailer (acting as an importer). According to the general safety requirement, all these actors must have in place measures to guarantee the safety of the product they place on the EU market. As a result, the responsibility for a non safe product put on the EU market does not fall on the suppliers in developing countries but on the EU importer. However, any EU importer may pass his responsibilities ultimately to their suppliers. In addition, EU producers and distributors must provide EU consumers with the necessary information in order to assess a product's inherent threat (e.g. through labelling or use instructions), particularly when a potential threat is not obvious. Furthermore, EU producers and distributors must take all necessary measures to avoid threats (e.g. product withdrawals or even recalling products that have already been supplied to consumers). If EU producers or distributors discover that a product is not safe, they need to notify the competent authority. It is therefore important that suppliers in developing countries make sure that their products comply with the general EU safety requirements.

## Further information

Information on latest RAPEX recalls can be accessed at;  
[http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

<b>EU/International legislation: Endangered species (CITES)</b>
<b>Product Category: Products made of plant or animal material</b>
<b>Product Standard/ Technical Regulation: Regulation (EC) 338/97, Regulation (EC) 865/2006</b>
<p><b>Rationale/ Associated Issues</b> The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) lays down provisions for the worldwide protection of endangered species of flora and fauna. These provisions constitute controls on international trade in specimens of these species and are the basis of a worldwide policy on protection of endangered species. CITES also prohibits or restricts the trade in products containing material from endangered species. This applies especially to leather articles, handicrafts, jewellery, flowers, plants, furniture and antiques.</p>
<p><b>Scope</b> The EU has implemented the requirements established in CITES by means of 2 Regulations, regularly updated after each CITES conference: 1. Regulation (EC) 338/97 on the protection of species of wild fauna and flora regulates the trade in species and gives a detailed list of species of which trade is prohibited, restricted or bound to certain rules. 2. Regulation (EC) 865/2006 concerning the implementation of Regulation (EC) 338/97 stipulates the administrative and technical details (design, use of permits and certificates) and is therefore only of indirect importance to importers and manufacturers. Further, the EU has also set import restrictions additional to those established by CITES relevant for manufacturers or exporters outside the EU. The ITTO-CITES Program for Implementing CITES Listings of Tropical Timber Species ensures that international trade in CITES-listed timber species is consistent with their sustainable management and conservation.</p>
<p><b>How to Comply</b> Roughly 5,000 species of animals and 28,000 species of plants are protected by CITES against over-exploitation through international trade. The species are grouped in three Appendices according to how</p>

threatened they are by international trade. Listing of species and the relevant Appendices appear at <http://www.cites.org/eng/app/appendices.shtml>. National contact points are listed at [http://www.cites.org/common/directy/e\\_directy.html](http://www.cites.org/common/directy/e_directy.html). Producers who utilize plant and animal material which may constitute endangered species should verify with their national contact point and contact points in the importing company whether these species are prohibited, subject to licensing requirements or quotas, require import and/or export permits or can be freely traded.

## Implications for Caribbean artisanal producers

Most Caribbean countries are signatories to the CITES Convention. This means that they have established national contact points which are available to provide further information. Producers using supplies of leather, animal products, dried flowers and timber need to consult these contact points to ensure that they are derived from sustainable sources and that the export process will be permitted as well as entry into an importing market will be allowed.

## Further information

CITES Homepage <http://www.cites.org/>

Appendices <http://www.cites.org/eng/app/appendices.shtml>.

National contact points [http://www.cites.org/common/directy/e\\_directy.html](http://www.cites.org/common/directy/e_directy.html)

<b>EU legislation: Safety of non-edible products imitating food</b>
<b>Product Category: ALL</b>
<b>Product Standard/ Technical Regulation: Directive 87/357/EEC</b>
<p><b>Rationale/ Associated Issues</b> Product safety is key concern in EU policy. Products that appear to be other products than they actually are, pose safety risks for consumers. For instance, products that look like food but are in fact soaps, candles or other decorative articles cause a risk of poisoning or choking to young children because they can mistake them for food. In order to protect EU consumers in all Member States, the EU has enacted legislation that guarantees product safety with regard to products that resemble food.</p>
<p><b>Scope</b> In the EU, Directive 87/357/EEC prohibits the marketing, import and manufacture or export of products which appear to be other than they are and thus endanger the health and safety of consumers. The Directive only applies to products that look like foodstuff but that are not in fact edible, which possess characteristics that will lead to consumers, especially children, to potentially confuse them with foodstuffs. These are also called 'food imitating product'. As a result of the likeness, consumers may place them in their mouths, suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract. Characteristics to be monitored include: • form • packaging • odour • labelling • colour • volume • appearance • size The Directive obliges the Member States to withdraw products that are not in compliance from their markets.</p>

### Implications for Caribbean artisanal producers

Artisanal producers desirous of selling products into EU markets must ensure that where products are not edible, they cannot be interpreted in a way to mislead potential consumers, in particular children into thinking that they are edible. Examples of products rejected by the RAPEX monitoring system include candles in the shape of apples, erasers with a fruity smell and home decorations resembling fruits.

### Further information

Review examples of RAPEX recall at: [http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)



# EU legislation: Registration, Evaluation and Authorization of Chemicals (REACH)

Product Category: Products using chemicals in the production process

Product Standard/ Technical Regulation: Regulation (EC) No. 1907/2006

## Rationale/ Associated Issues

REACH, the regulatory framework for the Registration, Evaluation and Authorization of Chemicals is the chemical legislation of the EU that came into force on 1st June 2007 through Regulation (EC) No. 1907/2006. REACH is the Regulation in the EU on chemicals and their safe use. It deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances. The new regulation will be implemented in phases within the next 10 years. Presently, REACH requirements for registration are in effect. REACH will establish a new single regime throughout the 27 EU Member States for existing and new substances and requires manufacturers in the EU and EU importers of substances/preparations to register them. The Regulation is continually evolving and comprises almost 900 pages in addition to other documents, guidance papers and opinions that can be found on Internet.

REACH assigns responsibility to the EU industry in compelling it to manage the risks from chemicals and to provide safety information on the substances. This means that manufacturers, importers and downstream users located in the EU will be required to gather and provide information on the properties of the substances and/or preparations they work with. The Regulation further introduces a new European Chemical Agency (ECHA) established in Helsinki, Finland, which will be managing the registration of substances through a database. The European Chemical Agency will have an important role in the evaluation and authorization of substances. The agency is also a helpdesk for questions and has specific capacity to answer questions from developing countries.

REACH defines an article as: “an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does”.

## Scope

The following products are included in REACH:

- .       •       substances, such as base chemicals, specialty chemicals, metals, additives, solvents,
  - .       •       monomers and natural substances if they are chemically modified
  - .       •       mixtures or preparations of chemical substances, for instance cleaning products,
  - .       •       formulated process chemicals, paints and motor oils
  - .       •       articles which contain substances which are intentionally released during their use,
- for  
example the fragrance in a scented candle

- articles which contain dangerous substances which are not intentionally released during their use, such as phthalates in garments
- substances in products/containers, such as ink in cartridges
- substances which are on a candidate list of "*substances of very high concern*"
- new substances

#### *Substances released from articles*

For substances that are intentionally released, for example the fragrance from a scented candle, the substances need to be registered if:

- the substance is not yet registered for that application
  - traded over 1 tonne/yr per producer/importer
- For substances in articles that are unintentionally released, for example phthalates in garments, only dangerous substances need to be notified from 1st June 2011 onwards. A list of those dangerous substances is published.

### **How to Comply**

EU importers have the main responsibility for registration, so producers are not directly involved and can wait until an EU buyer requests data on the chemicals used in the process or which are still traceable in your product. They can also anticipate on the possible request of EU buyers by the following actions:

- Create an inventory of all chemicals used, i.e. 1) all substances or 2) substances in preparations or 3) substances that can be released in the final products.
- It might be necessary to check your suppliers for additional data as well.
- Check the website of the European Chemicals Agency to find out if the substances or uses

in your inventory are exempted from the registration under REACH. • Identify for each substance on its own or in a formulated product the volume per EU importer. If a chemical substance in these inventories is imported into the EU  $\geq 1$  tonne/year it needs to be pre-registered and registered by the EU importer. Where this is not done the producer can recruit an EU based representative to conduct this process on their behalf.

**Implications for Caribbean artisanal producers** In general companies outside the EU (1) manufacturing substances or preparations or (2) using substances or preparations that still can be found in the finished product, are not directly accountable, however: EU importers might request additional information from their suppliers in order to do their own registration for REACH. Producers should be aware of the following: • in some cases you will have to refer to your own suppliers to get all data together • When costs are involved for EU parties, for example to create a dossier, part of the costs might be passed through to the supplier. • In a few cases EU importers might request from their suppliers to do the registration themselves, then they are directly involved REACH allows manufacturers from outside the EU to pre-register and register their chemicals. This is possible by appointing a representative within the EU who will act on behalf of the manufacturer outside the EU. An **only** representative can represent one or several non-EU companies. The EU importer might need hazard data, safe use information and volumes on the chemicals you used. So, an inventory of the substances, preparations and articles that contain substances which will be foreseeable released from the articles will be a very possible requirement from your EU importer. Where chemicals are not produced in-house but purchased, producers are responsible for obtaining the specific data from supplier to complete the filing. Producers must therefore be vigilant about maintaining an inventory of chemical substances used in the process.

**Further information** The REACH helpdesk of the European Chemicals Agency will give advice to companies in Third Countries.

## EU legislation: Dangerous substances in decorative articles

**Product Category:** ALL

**Product Standard/ Technical Regulation:** Directive 97/64/EC, Directive 76/769/EEC

**Rationale/ Associated Issues:** Lamp oil is used to give colour and perfume in decorative oil lamps and candles. If ingested, the oil can be toxic and cause injury to the lungs. Until now, a number of EU Member States have experienced a death record of two to three deaths per year caused by the ingestion of lamp oils. The majority of incidents involve young children, who appear to be attracted to the colour and smell of the oil and drink the oil directly from the lamp confusing lamp oils with lemonade. In order to prevent these kinds of situations, the EU has laid down legislation which sets specific safety requirements for lamp oil.

**Scope** Outline of Directive 97/64/EC, amending Directive 76/769/EEC, prohibits the use of liquid substances or preparations, which are classified as dangerous in: 1. Ornamental objects intended to produce light or colour effects (e.g. in ornamental lamps and ashtrays). 2. Tricks and jokes. 3. Games for one or more participants or any object intended to be used as such, even with ornamental aspects. Furthermore it is prohibited to add a colouring agent or perfume to substances and preparations that: present an aspiration (inhalation) hazard and are labelled with R65m which means "Harmful: may cause lung damage if swallowed" and can be used as fuel in decorative lamps, and are placed on the market in packaging of 15 litres or less.

**How to Comply** In addition to other EU legislation on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such substances and preparations, must be marked legibly with the following phrase: "Keep lamps filled with this liquid out of the reach of children".

## Implications for Caribbean artisanal producers

Producers should refrain from using substances which are toxic and dangerous to provide colouring effects in products. Where the dangers are unknown testing must be used to provide the appropriate labelling. In addition to lamp oil there are a number of other dangerous substances listed including benzene, lead sulphates and cadmium.

## Further information

Directive 76/769/EEC: <http://www.dehp-facts.com/upload/documents/webpage/document32.pdf>; <http://www.reach-compliance.eu/english/legislation/docs/launchers/launch-76-769-EEC.html>

<b>EU legislation: Azo dyes in textile and leather articles</b>
<b>Product Category: Textiles and Leather articles which may come into direct and prolonged contact with the human skin or oral cavity</b>
<b>Product Standard/ Technical Regulation: Directive 2002/61/EC, Directive 76/769/EEC</b>
<p><b>Rationale/ Associated Issues</b> Azo dyes are synthetic organic compounds characterized by containing one or more nitrogen-nitrogen double bonds called azo groups in their chemical structure. They are the most important chemical class of dyes, representing 60-70 % of all dyes. They are usually red, brown or yellow. Azo dyes are commonly used as colouring agents in the textile and leather industry, especially in developing countries. In the 1990's, EU legislation was introduced restricting certain azo dyes. Azo dyes are manufactured from aromatic amines. It is important to note that some of them can split off carcinogenic amines, such as benzidine, which may be absorbed through skin and the respiratory and intestinal tract. Certain aryl amines pose cancer risks. Non-fixed, water-soluble azo dyes can also come into contact with skin through perspiration fluid. In other internal parts, for instance in the liver, azo compounds can be broken down by certain enzyme systems. The legislation is laid down in Directive 2002/61/EC, amending Directive 76/769/EEC on the marketing and uses of dangerous substances and preparations. For this reason, the European Union laid down legislation to prevent exposure to these hazardous aryl amines. This indirectly implies that azo dyes containing aryl amines can no longer be used to dye textile and leather products that come into contact with the skin. The aim of the Directive is to protect the consumers' health in the EU. The Directive is applicable to all textile and leather products that may come into direct and prolonged contact with the human skin or oral cavity.</p>
<p><b>Scope</b> Some examples of products falling within the scope of the Directive are listed below. The items listed do not constitute an exhaustive list. • clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags • footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, • purses worn around the neck • textile or leather toys and toys which include textile or leather garments</p>

• yarn and fabrics intended for use by the final consumer The Directive establishes that the products covered by the legislation may not contain the 22 amines listed in Table 1 (below) in a concentration above the threshold limit of 30 ppm (detection limit). All parts of a product should comply with this limit and this limit applies to each amine separately (e.g. a textile shoelace of leather footwear needs to comply with the limit of 30 ppm, as well as the leather parts of footwear). Textile articles made of recycled fibres are allowed an exception. In this case, the threshold limit equals 70 ppm for the listed amines if the amines are released by residues deriving from previous dyeing of the same fibres Azo dyes may release one or more of the

aromatic amines listed in Table 1 below.

Table 1. List of aromatic amines

	CAS number <sub>1</sub>	Index Number	EC number	Substance name
1	92-67-1		202-177-1	Biphenyl-4-ylamin, 4-aminobifenyl , Xenylamine
2	92-87-5	612-042-00-2	202-199-1	Benzidine
3	95-69-2		202-441-6	4-chloro-o-toluidine
4	91-59-8	612-022-00-3	202-080-4	2-naphthylamine
5	97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene 4-amino-2',3-dimethylazobenzene 4-o-tolylazo-o-toluidine
6	99-55-8		202-765-8	5-nitro-o-toluidine
7	106-47-8		203-401-0	4-chloroaniline
8	615-05-4		210-406-1	4-methoxy-m-phenylenediamine
9	101-77-9	612-051-00-1	202-974-4	4,4'-methylenedianiline 4,4'-diaminodiphenylmethane
10	91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine
11	119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine o-dianisidine
12	119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine 4,4'-bi-o-toluidine
13	838-88-0	612-085-00-7	212-658-8	4,4'-methylenedi-o-toluidine
14	120-71-8		204-419-1	6-methoxy-m-toluidine p-cresidine
15	101-14-4	612-078-00-9	202-918-9	4,4'-methylene-bis- (2-chloro-aniline) 2,2'-dichloro-4,4'-methylenedianiline
16	101-80-4		202-977-0	4,4'-oxydianiline
17	139-65-1		205-370-9	4,4'-thiodianiline
18	95-53-4	612-091-00-X	202-429-0	o-toluidine 2-aminotoluene
19	95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenediamine
20	137-17-7		205-282-0	2,4,5-trimethylaniline
21	90-04-0	612-035-00-4	201-963-1	o-anisidine 2-methoxyaniline
22	60-09-3	611-008-00-4	200-453-6	4-amino azobenzene

A CAS number is a unique identifying number assigned to chemicals by the Chemical Abstracts Service

**How to Comply Compliance with EU legislation** EU importers are formally responsible for complying with the azo dyes legislation. However, since the EU importers do not determine which dyes are used in the process, they are likely to set purchase requirements, or binding guarantees in their contracts. But also without the pressure from an importer, it is sensible from a marketing point of view, to take the legal risks for the importer into consideration and comply with the legislation in order to minimize risks of faulty products. An EU importer may also demand an azo-safe certificate from its suppliers in order to guarantee no presence of prohibited azo dyes. In that case, the producer must bear the costs involved. Test methods for azo dyes have been established in Directive 2004/21/EC, amending Directive 76/769/EEC. These are the official test methods in the EU, and should be used to test your products targeting the EU market. The following test methods are listed in the Directive: 1. CEN Leather — Chemical tests — Determination of certain azo colorants in dyed leathers. Reference: CEN ISO/TS 17234:2003 2. CEN Textiles — Methods for the determination of certain aromatic amines derived from azo colorants — Part 1: Detection of the use of certain azo colorants accessible without extraction. Reference: EN 14362-1:2003 3. CEN Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 2: Detection of the use of certain azo colorants accessible by extracting the fibres. Reference: EN 14362-2:2003 **Testing on azo dyes** Testing facilities on banned azo dyes are already available in some developing countries. If it is not possible to test in the country of production, then it is feasible to perform these tests in Europe. Look for certified laboratories, like TÜV in Germany, TNO in The Netherlands or BTTG in the United Kingdom.

The costs of testing depend on the number of samples needed. **All the different parts of the finished product should be tested**, and if there are several colours involved, it is not necessary to test them all separately. Only if the general test proves that there are banned azo dyes in the product, then more tests should be done. The EU legislation on azo dyes (Directive 76/769/EEC) lays down the test methods to be used in order to check compliance with the requirements. It is recommended to use these test methods, because it might be the case that a different method results in a (slightly) different outcome of the test.



## Implications for Caribbean artisanal producers

The best way to avoid problems with banned azo dyes is to use only dyes which cannot split off the hazardous amines. The following advice can be given to producers:

- .       •       Make an inventory of the dyes used in your production process and include the products you buy and may contain dyes in your inventory.
- .       •       If possible, cross-check the dyes used in your company with the lists of dyes given in Table 1. Refrain from using these dyes and change supplier policy if the EU market is a major target market.
- .       •       Ask your suppliers for azo-safe certificates. Your EU buyer might request them from you
- .       •       Use dyestuff supplied by reputable producers, who provide the Colour Index Numbers<sup>1</sup>, the generic names and material data sheets (MSDS) indicating the hazardous properties and preventive measures to be taken. Good example of these kind of producers are the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD)<sup>7</sup> members.
- .       •       If you want to test your product, choose recognized certified (accredited) laboratories and ask them to use the test methods that are specified in the EU legislation.
- .       •       Ask your importer to send you the latest information on the legislative requirements on azo dyes or check the CBI database for the latest EU legislation.
- .       •       Check whether it is possible to use of natural dyes instead of azo dyes in your product.

## Further information

Directive 76/769/ [http://eur-](http://eur-ex.europa.eu/LexUriServ/site/en/oj/2002/l_243/l_24320020911en00150018.pdf)

[ex.europa.eu/LexUriServ/site/en/oj/2002/l\\_243/l\\_24320020911en00150018.pdf](http://eur-ex.europa.eu/LexUriServ/site/en/oj/2002/l_243/l_24320020911en00150018.pdf)

Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers

<http://www.etad.com/>

## **EU législation: PentaBDE products**

**Product Category:** Furniture and Products utilizing flexible polyurethane foam

**Product Standard/ Technical Regulation:** Directive 2003/11/EC, Directive 76/769/EEC

**Rationale/ Associated Issues** Directive 2003/11/EC (amending Directive 76/769/EEC) covers the restriction of two brominated flame retardants: pentabromodiphenyl ether (pentaBDE) and octabromo – diphenyl ether (octaBDE). Of these two, only pentaBDE, used in the manufacture of flexible polyurethane is relevant to furniture and upholstery. Risk assessments have identified that the compound poses a threat to the environment and to human health as it is bioaccumulative and found in breast milk in increasing concentrations.

**Scope** The Directive is applicable to “articles” in general, where these substances are present in products or used in the production process of products. Directive 2003/11/EC, effective as of August 15th 2004 prescribes that articles may not be placed on the market if they, or flame retardant parts thereof, contain either pentaBDE or octaBDE in concentrations higher than 0.1% by mass. An additional flame retardant, decaBDE, has already been restricted by national legislation in Sweden and may be widened to EU-wide legislation following the results of a risk reduction strategy currently being undertaken.

**How to Comply** Testing of materials to ensure compliance may be required by buyers in relation to exports to Europe.

**Implication for Caribbean artisanal producers** Polyurethane foam is manufactured in several countries of the Caribbean region. Enterprises wishing to export furniture or other items made of foam to the European market should engage suppliers in dialogue concerning how flame retardant properties are imparted and aim to identify whether these compounds are present. In the absence of a clear indication, testing should be done to eliminate the uncertainty in advance of marketing in Europe.

**Further information** Directive 2003/11/EC

[http://www.ncel.net/news\\_uploads/117/EuropeanUnion.directive.pdf](http://www.ncel.net/news_uploads/117/EuropeanUnion.directive.pdf)

<b>EU legislation: Creosote oil in wood products</b>
<b>Product Category: Products made of wood</b>
<b>Product Standard/ Technical Regulation: Annex XVII to the EU Regulation (EC) 1907/2006</b>
<p><b>Rationale/ Associated Issues</b> Creosote is a mixture of many chemicals and is used, among other applications, to preserve wood. Creosote protects against rot and insects, colours and provides a degree of water repellency. EU legislators have determined that some of the components of creosote are poorly degradable and may enter the environment as a result of the use of treated wood. Creosote may also be harmful to certain organisms in the environment. Moreover, in the late 1990s, research showed that human exposure to creosote could cause cancer, which led to a tightening of existing legislation in the EU. Since 1 June 2009, the restriction of the use of creosote oil in wood products is laid down in Annex XVII to the EU Regulation (EC) 1907/2006 on the registration, evaluation and authorization of chemicals (REACH), which is directly applicable in all Member States. Until this date, this matter was regulated by means of Directive 76/769/EEC on the marketing and use of certain dangerous substances and preparations and its amendments, which is repealed by the REACH Regulation.</p>
<p><b>Scope</b> The substances falling within the scope of the Directive are · Creosote · Distillates (coal tar), upper · Creosote oil · Anthracene oil · Distillates (coal tar) naphthalene oils · Tar acids, coal, crude · Creosote oil, acenaphthene fraction · Creosote, wood · Distillates (coal tar) naphthalene oils · Low temperature tar oil, alkaline The Regulation establishes a prohibition of the marketing of wood treated with the substances and preparations containing one or more of the substances listed above.</p>

**How to Comply** The Regulation establishes a prohibition of the marketing of wood treated with the substances and preparations containing one or more of the substances listed above. It provides for certain exemptions from the general prohibition. The substances above and related preparations are allowed if they are used for wood treatment in industrial applications.

### Implication for Caribbean artisanal producers

Annex XVII to the EU regulation (EC) 1907/2006 states that the products listed above “shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market.” The Directive expressly states that treated wood is never to be used in toys or garden furniture.

### Further information

Annex XVII to the EU regulation (EC) 1907/2006 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF>

## Conclusion

There is an abundance of EU legislation which could potentially affect artisanal products seeking entry to Europe. Many producers view these legislative hurdles and technical standards as technical barriers to trade. However, as discussed in this report, it is also possible to make the case for the need for these market requirements in order to regulate the protection of consumers and the environment from potential dangers. At the very least, where Caribbean producers are interested in positioning themselves to take advantage of the potential market opportunities, they will have to familiarize themselves with these market requirements in order to engage European buyers in dialogue. The significant responsibilities which buyers hold under European law and the high levels of accountability to which they are held are an important feature of the market requirements. This means that engaging buyers in dialogue (in the product design and development phase where possible) provides the basis for successful market entry and future collaboration.

Marking and labelling are also critical, serving two major purposes. First, they aid the smooth distribution of products through the transport and logistics system. Labels should state the originating and destination addresses, as well as contact names and telephone numbers. Secondly, marking and labeling give information concerning the product. Appropriate labels should be attached to indicate, for example, that items are fragile and that they need to be kept upright. Without attaching these labels, the people handling the objects and crates will not be aware they have to be careful. The use of the pictorial marking "FRAGILE" can be used when product content is prone to breaking/ damaging/scratching. Special care must be taken when packing products which are very vulnerable to water damage.

The second reason for marking and labelling is to inform the consumers about the product. Today's consumer wants to know exactly what he or she is buying. Therefore, it is important to mark the product's brand name, special materials, name/sign of the manufacturer and guarantee of originality, according to the market segment for which the product is intended. A label on the article has to provide the necessary data in a language comprehensible for the target market. In general, the label should state material(s) used, qualities, country of origin and, if applicable, size in centimetres or volume in litres and instructions for use. Moreover, labels and package can both be used for sales promotion of other articles of the manufacturer in the same category. Positive sales arguments, which should be indicated on the product if applicable, are environmentally friendly, produced from recyclable material, etc. Additional information on packaging can be found at the website of ITC on export packaging: <http://www.intracen.org/ep/packit.htm>.