PART 1

Chapter 2

Overview of EC Policies and Implications for Commonwealth Exporters

Introduction

The Single European Market is based on a complex legislative programme which may appear daunting to Commonwealth exporters wishing to do business with the EC. Fortunately not all legislation from Brussels needs to be dealt with in great depth. The EC's approach to product standardisation affects present and potential Commonwealth exporters. Policies on the environment, consumer protection, health and safety, product liability, etc. indirectly but greatly affect marketing within the EC. They serve as guidelines/parameters to be kept in mind when considering whether a product can be successfully sold to the EC market. Decisions are therefore made not just on the basis of value for money but public concern is taken into account. European legislation serves as a means of implementing rules which otherwise would be difficult to enforce on a national level. Higher standards of health and safety, for example, may be considered an extra cost and products from one state may become uncompetitive due to higher prices.

1. Product Standardisation

Producers, suppliers, purchasers and, most of all, consumers often want to be assured that they get uniformity and consistency in quality of the products. Member States in the EC have instituted the following arrangements in order to ensure quality:

- ***TECHNICAL REGULATIONS*** lay down the legal requirements enacted by national parliaments mainly in the interests of health, safety and the environment;
- ***STANDARDS*** are produced by private national standardisation bodies (such as BSI in Britain or the DIN in Germany). These standards are only voluntary codes, but they often assume a quasi-legal status because of their use as a reference in technical regulations.
- ***TYPE TESTING AND CERTIFICATION*** is used to check that a product complies either with voluntary standards or with statutory regulations.

Differences in technical regulations, standards, testing and certification among Member States represent technical barriers to trade within the EC. Manufacturers are unable to benefit from economies of scale. Differences in standards force them to produce for national rather than Community-wide standards. Varying systems of testing and certification can result in repeated checks on the same product. This usually entails considerable extra cost for potential EC sellers. These problems apply to Commonwealth exporters as well.

As free movement of goods is at the heart of the drive to create a Single European Market, the EC aims to eliminate such barriers to trade by a new approach on product standardisation and technical regulation. The key elements of this approach are:

1. Establishment of compulsory requirements essential to the marketing of products

Highly detailed standards usually apply to specific product categories. They are generally referred to as vertical standards as they apply to products within a very specific narrow band. The "new approach" followed by the EC establishes a set of essential requirements for general product groups on a horizontal level.

Legislative harmonisation is limited to the adoption of these essential safety requirements (or other requirements in the general interest) which products put on the market must conform in order to enjoy free movement throughout the Community.

2. ***Creation of harmonised European Standards by European Standardisation Bodies***

The task of drawing up the technical specifications needed to conform to the essential requirements is entrusted to competent standardisation bodies. The main European standardisation bodies are CEN and CENELEC.

The EC will therefore only lay down essential requirements, leaving the guidelines for technical applications to be worked out by a European standardisation organisation. The essential requirements are drawn up by civil servants and experts of all Member States. National governments, producers, buyers, research institutes, consumers, employees, employers, national standardisation institutes and approval and certifying institutes are consulted over a period of time before the final legislation is issued. These international requirements are binding and must be converted into legislation and regulation by the national governments of the EC.

Technical specifications issued by the European standardisation bodies CEN and CENELEC become European standards or norms (EN). It often takes several years before these are agreed and established, as they are drawn up in collaboration with national standardisation organisations. Setting standards is therefore a matter of seeking consensus among those national organisations. These bodies agree to adopt these European standards and to withdraw any existing conflicting standards.

These technical specifications are not mandatory and maintain their status as voluntary standards. A manufacturer therefore has a choice of ignoring these European norms, but he must prove in some way that his product meets the essential requirements laid down by EC legislation. There are therefore two basic routes the manufacturer can take to demonstrate conformity with essential requirements:

1. **EC Declaration of Conformity**

- Manufacturer with a full quality control system in place may make a declaration that the product conforms to Directive requirements. The quality control system is then inspected by an approved body notified by a Member State
- Manufacturer must make a detailed statement concerning design, manufacture, and performance of product; and a design dossier will also be examined by a notified body
- Manufacturer must submit to surveillance by the notified body, to ensure that the obligations of the approved quality system is fulfilled

(Manufacturer not required to use EC standard)

2. **EC Type Examination** (This goes together with an EC Verification and EC Declaration of Conformity to Type)

EC Type Examination

- This is a procedure by which an approved body of a Member State examines a sample (type) of the product and certifies that it satisfies the requirement of the EC legislation.

In some product categories for example active implantable medical devices the following declarations are required:

EC Verification

- Procedure carried out by a notified body, to establish by random sampling that a product conforms to the sample approved under "type examination" procedure.

EC Declaration of Conformity to Type

- Procedure which a manufacturer who has chosen the type examination route guarantees and declares that the product conforms to that approved in the type examination certificate and meets with the Directive requirements.

For Commonwealth exporters the second route is more advisable. To set up a full quality system is a lengthy and costly undertaking. There is also no assurance that products will be accepted as conforming to essential requirements.

Type examination may be a simpler route to follow. There is more certainty that products will be approved as EC standards will be the basis of production. Difficulties may arise if there are a number of models as each model or each change in specification will need to be approved.

For most products approval of products can be obtained from EC Members of the European Committee of Standardisation (CEN). For manufacturers outside the EC, application for approval can be made by the manufacturer himself or by the manufacturer's EC representative or importer.

Products which conform with the demands of the essential requirements of safety, health, environment and consumer protection are allowed to bear the CE mark. This mark of approval stands for "Conformite Europeenne". Within the next few years about 40% of all products traded in the EC will have to bear the CE mark. This applies to products manufactured outside the EC. Once legislation is implemented on a national level, products which do not conform to the essential requirements may no longer be traded within the EC.

In the case of a great number of products which entail little risk, the producer or EC importer may himself draw up a declaration stating that the product fulfils the essential requirements established. He may affix the CE mark without involvement of a third party. However, there are other products for which this procedure is not applicable. In which case the importer or manufacturer needs a certificate from an independent inspection institute. Only when he has obtained their approval may the product be affixed with the CE mark.

Agreement on standards is expected to take a long time to achieve. As a transitional measure, the mutual recognition of national standards has been accepted by EC Member States until approved European standards are created. Products approved by national authorities of one Member State must be allowed to be marketed within others. The EOTC (European Organisation for Assessment and Certification) was founded on 28th November 1990 to encourage and manage the development of European Certification System. The EOTC ensures that the assessment given in each State is sufficient and comparable. It should be noted however that the European structure for certification and assessment only applies to legal demands. It is envisaged that, in the future, these organisations will exert a strong influence on the voluntary forms of certification and assessment.

A data bank called "Certificat" has recently been set up to enable one to find out which certification systems and procedures are used in the different European countries and which institutions need to be contacted for assessment. The following information will be offered by Certificat:

- general information of certification in individual countries and on a European level
- practical information on the institutions, which play an active role in the issuing of certificates and assessment reports, including laboratories and inspection institutions
- descriptions of systems and procedures for certification of quality guarantee and of the technical and administrative basis according to the kind of product.

Certificat is managed by AFNOR, the French standardisation body. Full details can be found in Part III.

2. General Product Safety

The EC has issued legislation which when implemented will impose a requirement on producers to place only safe products on the market. It applies to all products which are not subject to other Community laws already containing safety requirements. Products such as toys, machinery, gas appliances, etc. already have specific rules. These will have to meet the safety requirements specified in the relevant Directives. However, where Community law governs only specific aspects of a product's safety, that law will continue to apply in respect of the specified aspects and the general safety requirement will apply to its other aspects.

The following points in particular will be considered in assessing safety of the product:

- The characteristics of the product, including its composition, packaging, instructions for assembly and maintenance
- the effect on other products, where it is reasonably foreseeable that it will be used with other products
- the presentation of the product, the labelling, any instructions for its use and disposal and any other indication or information provided by the producer
- the categories of consumers at serious risk when using the product, in particular children.

Legislation also requires producers to take appropriate measures to be informed of risk or prevent possible dangers once the product is in the market. For example, marking of products or product batches so that they can be identified and recalled quickly, sample testing of products, investigation of product complaints.

Products can be denied entry into the EC by customs authorities if they are not marked in accordance with rules of product safety or if there is reason to believe the products could cause possible harm to health and safety.

Further legislation has been implemented so that if a consumer who has suffered damage shows that the injury was caused from using the product, consumers can sue the manufacturer if damage exceeds 500 ECU. It is up to the producer to prove that the product satisfied safety requirements. For this reason assessment marks, or certifications from a notified body, although not required by legislation, can prove to be advantageous as they provide a way of proving the manufacturer's innocence. Although manufacturers from countries outside the EC will not be held directly liable, importers will need to be more careful when selecting imported products which may cause injury. Exporters must therefore be aware of and comply with EC accepted safety standards if the products are to be marketed in the EC.

3. Quality

There is growing concern for quality in Europe. The International Standards Organisation has established norms for quality assurance under the ISO 9000 series. This establishes generally applicable rules for establishing and controlling a quality system. The EC has adopted this standard under EN 2900-29004. Manufacturers of products which require an EC Declaration of Conformity must show proof of a full quality control system and meet requirements of this standard.

The norms of the ISO 9000 series are as follows:

ISO 9000 clarifies the difference and connection of the main principles of quality care. It provides guidelines for choice and utilisation of quality systems according to ISO 9001-9004.

ISO 9001 establishes a model for quality assurance when specific demands are made on design and the requirements of the products are stated in functional terms. The model aims to avoid defects at all stages from design to after-care of the product.

ISO 9002 establishes a model for quality assurance when the suppliers have to demonstrate competence to control the processes which determine the delivery of goods. It provides quality assurance during manufacture and installation of products.

ISO 9003 provides a model for quality assurance for final approval and testing of the product when it is finished.

ISO 9004 describes a number of basic elements which can be used to implement an internal quality care system.

Under the framework of ISO 9000-9004 Commonwealth exporters must bear in mind the following concepts:

Quality Management

The objectives of a (company's) organisation in relation to quality, as well as the ways and means which lead to the realisation of these objectives, as these are formally expressed in a statement from the management.

Quality Care

The aspect of the entire way the management functions, which determines the establishing and implementation of the quality management.

Quality System

The organisational structure, responsibility, procedures, processes and arrangements for the implementation of quality care.

Quality Control

The operational techniques and activities which are utilised, so as to ensure that the quality demands are fulfilled.

Quality Assurance

The entirety of all planned and systematic actions necessary to instil sufficient confidence that a product or service conforms to the set quality demands.

Costs of implementing a quality guarantee system can be quite high but it does offer a manufacturer a competitive edge. The services of a quality expert will be required and implementation covered take several months. It must be remembered that each organisation's quality system will be different as it depends on a company's objectives in relation to quality, its product or service and its specific method of working.

Many Commonwealth countries are members of ISO National Standardisation Institutions and are familiar with ISO 9000. Alternatively, exporters or manufacturers can contact the European Standardisation Committee or any of its members as detailed in Part III.

Manufacturers from Commonwealth countries must be fully aware of the high quality standards demanded by markets in the EC. Some Commonwealth markets may not be so demanding where choice is limited and price more than quality can be a decisive factor in the purchase decision. If Commonwealth countries are to be competitive in Europe they must meet the quality expectations of their intended market.

4. The EC and the Environment

The Single European Act (SEA) introduced specific Treaty rules on the environment. Although the EC had been taking measures in the environmental field ever since a Declaration by EC heads of government in October 1972 called for an action programme on the environment, the SEA provides an

explicit Treaty basis for such activity for the first time.

The EC's environment policy has the following objectives:

- to preserve, protect and improve the quality of the environment
- to contribute to protecting health
- to ensure a prudent and rational utilisation of natural resources.

The underlying principles of EC action are that preventative action should be taken, that the source of environmental damage be clearly identifiable and that the polluter should pay. Environmental protection requirements are to be a component of other EC policies.

In determining measures relating to the environment, the EC is to take account of:

- available scientific and technical data
- environmental conditions in the different parts of the Community
- the potential benefits and costs of action or lack of action
- the economic and social development of the Community as a whole and the balanced development of its regions.

This policy has a direct effect on some product categories. Chemicals harmful to the environment are being closely monitored and appropriate legislation is being prepared. Businesses have begun to specify less toxic ingredients to prevent pollution. The EC's policy on the environment has also resulted in the following legislation which would effect almost all product categories.

Packaging

Packaging is an essential part of almost any product category. Not only is packaging a means of protecting the product for transport and handling but it is also an important marketing tool. Commonwealth exporters must see packaging as part of the product and not just as an added extra particularly when selling to the developed markets of the EC.

The EC's policy on the environment has added a further dimension to the subject of packaging. It is estimated that more than 100 million households in the EC produce waste from consumer packaging, in addition to industrial and commercial enterprises. Total EC packaging waste is estimated as currently being 15 million tonnes per year. The environmental effects of such a large amount of packaging waste have caused major concern within the EC as only about 9 million tonnes (18% on average) is said to be recycled.

As a result, legislation on packaging and packaging waste management is before the European Commission and is forecast to take effect mid-1994. Member States must introduce a collection/return and management system for packaging waste within 5 years of the legislation. To provide free movement of goods where packaging waste can be collected and recycled anywhere in the Community, manufacturers and users of packaging must meet essential requirements of packaging laid down by EC legislation. Packaging must therefore be re-usable, recyclable or otherwise recoverable. Commonwealth exporters must take account of these requirements.

The packaging legislation covers the following areas:

1) **Manufacture and Composition of Packaging**

- packaging volume and waste must be limited to the minimum adequate amount to maintain necessary levels of safety and consumer acceptance

- packaging must be designed, produced and marketed so as to permit its re-use or recovery and to minimise its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of
- noxious metals and other hazardous substances as constituents of the packaging material or of any of the packaging components must be limited to such a level as to minimise their presence in emissions, ash on incineration or land-fill
- the total concentration levels of lead, cadmium, mercury and hexavelant chromium present in packaging or packaging components will be limited by this EC legislation.

2) Marking

- packaging which is re-usable or recoverable must bear the mark shown below:

FIGURE 2.A

1. (a) Reusable Packaging

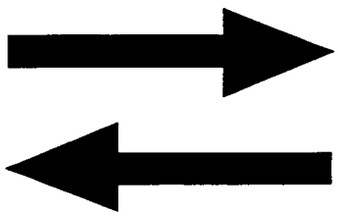


FIGURE 2.B

1. (b) Recoverable Packaging

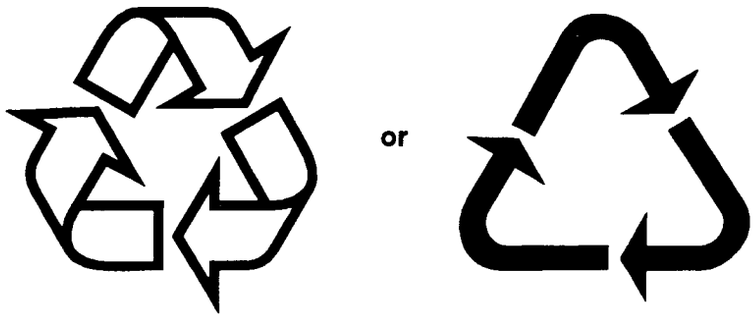
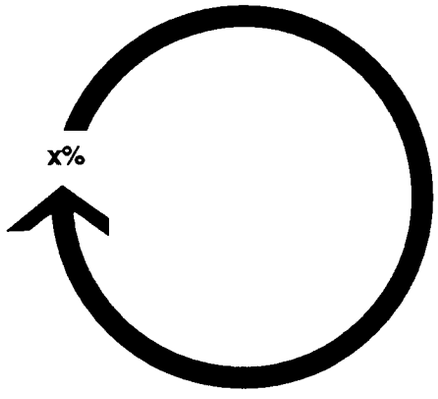


FIGURE 2.C

1. (c) Packaging made partly or entirely of recycled materials



x% = percentage of recycled material used in the manufacturing of the product.

Aside from these essential requirements European standards are to be expected on the following:

- shapes of packaging for specific products to promote re-use or recovery
- modular distribution packaging
- product specifications for use of recycled material in packaging.

Member States of the EC are also expected to implement national measures to promote the following:

- limitation of excess use of packaging
- packing concentrated products where feasible
- substitution where possible of small contents packaging units for bigger ones or by bulk services
- adoption of product specifications to promote use of recycled materials in packaging and other products.

This new legislation will not take effect until 1994. Packaging manufacturers and users of packaging must not assume that they have all the time to adapt packaging to the requirements of this legislation. EC Member States such as Germany, The Netherlands and France have already instituted their own national requirements with regards to packaging and packaging waste. At the present time for Commonwealth exporters to remain competitive it is best to keep abreast of national as well as EC developments on this matter.

Eco Labelling

In line with the EC's policy on the environment a scheme of "eco labelling" for consumer goods is now being developed in the EC which will provide an official label for approved "green" products. This scheme will provide an authoritative guidance to consumers who wish to chose products for environmental reasons. The eco labelling scheme aims to encourage the production of more environmentally friendly products and to facilitate trade in these products.

The Council of Environment Ministers set out a frame-work for a scheme whereby the eco label as shown below will be awarded to those products which have the best environmental performance within particular product categories.

FIGURE 3

The EC has begun the process of setting down the criteria which will be based on a "cradle to grave" analysis of the environmental performance of each product category. Only those products which meet these criteria will be allowed to carry the eco label.

Eco labelling criteria for the following product groups have been initiated:

- detergents
- hair spray
- soil improvers
- textiles - tee shirts and bed linen
- household cleaning products
- shampoos
- batteries
- refrigerators
- floor and wall tiles
- light bulbs
- paints and varnishes.

Although the scheme will be officialy launched in June 1993 it will take at least a year before the EC decides on definite criteria for the products mentioned above. Commonwealth exporters can ask their importers in the Community to apply for the award of an eco label to a competent body designated by the Member States. This is not compulsory but may prove to be an advantage in promoting a quality image.

Conclusion

Commonwealth exporters and all the various trade development bodies in the exporting countries must invest more effort in keeping up to date with these EC requirements. Remember the key issues:

- PRODUCT STANDARDISATION
- GENERAL PRODUCT SAFETY
- QUALITY ASSURANCE
- ENVIRONMENTAL LEGISLATION.