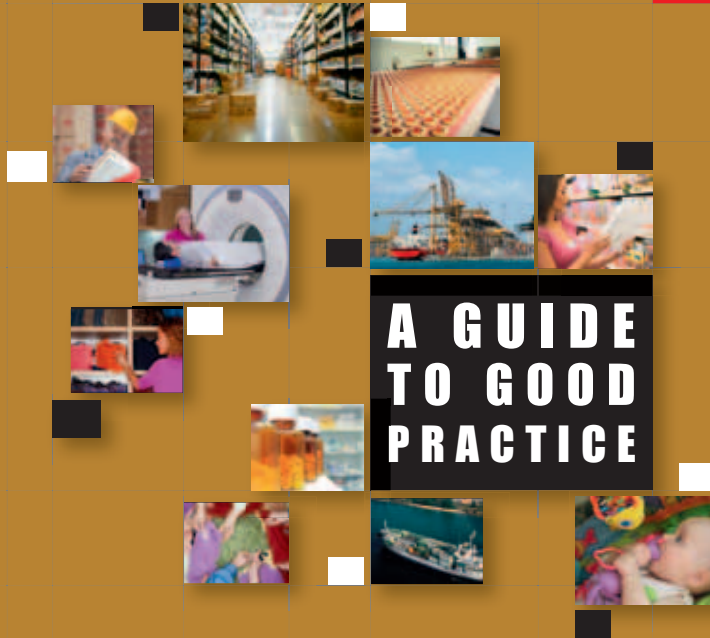




# A GUIDE TO GOOD PRACTICE



## PRINCIPLES AND PRACTICES IN PRODUCT REGULATION AND MARKET SURVEILLANCE



# A GUIDE TO GOOD PRACTICE

<b>INTRODUCTION</b> .....	<b>3</b>
<b>THE NEED FOR MARKET SURVEILLANCE</b> .....	<b>5</b>
<b>GOOD PRACTICE CRITERIA</b> .....	<b>7</b>
<b>SOUND REGULATORY PRINCIPLES</b> .....	<b>7</b>
<b>PREREQUISITES FOR GOOD PRACTICE</b> .....	<b>7</b>
<b>GENERAL GOOD PRACTICE CRITERIA</b> .....	<b>10</b>
<b>MARKET SURVEILLANCE METHODOLOGY</b> .....	<b>11</b>
<b>RESOURCES, COSTS AND BENEFITS</b> .....	<b>14</b>
<b>PRIORITIZING</b> .....	<b>17</b>
<b>NATIONAL, REGIONAL AND GLOBAL ISSUES</b> .....	<b>19</b>
<b>SECTORIAL EXAMPLES OF GOOD PRACTICE</b> .....	<b>25</b>
<b>ELECTRONIC AND ELECTRICAL PRODUCTS</b> .....	<b>25</b>
<b>MEDICAL DEVICES</b> .....	<b>32</b>
<b>FOOD AND AGRICULTURAL PRODUCTS</b> .....	<b>38</b>
<b>CHEMICAL AND PHARMACEUTICAL PRODUCTS</b> .....	<b>44</b>
<b>PERSONAL PROTECTIVE EQUIPMENT</b> .....	<b>49</b>
<b>TOYS</b> .....	<b>53</b>
<b>CONCLUSIONS</b> .....	<b>58</b>

This document was developed by the International Organization for Standardization (ISO) to assist regulators and market surveillance authorities.

It is especially intended for developing regions, to design market surveillance systems that conform to modern good practice criteria and that make the best use of the “CASCO Toolbox” of International Standards and other deliverables that have been developed to support good regulatory practice.

This document recognizes that there are vast differences between developing countries, and while they qualify as developing on economic data, they also utilize standards, regulatory and conformity assessment legal frameworks, working institutions and competent staff. Likewise, some countries classed as developed on economic data may also benefit from the guidance given in this publication.

# INTRODUCTION

This document is aimed at stakeholders in developing countries who have an interest in the proper conduct of market surveillance activities in the marketing of regulated products. It is also aimed at those developed countries which do not have fully developed market surveillance activities. It uses the term “market surveillance” to include both pre-market and post-market surveillance activities. It attempts to reflect modern good practices in the form of “good practice criteria”. Market surveillance authorities should aspire to follow these in their quest to enhance consumer protection, whilst taking account of the realities of limited resources affordability. There are also issues of varying levels of technological and conformity assessment infrastructure and, indeed, inconsistent levels of technical regulation sometimes found in their countries.

This document starts with a basic consideration of the reasons behind the need for technical regulation and market surveillance, and identifies some common good practices that are applicable to all market surveillance authorities. It goes on to consider these in the light of the resource limitations that many governments face. It takes into consideration the sometimes difficult issue of setting priorities for consumer protection in



the face of competing demands for limited funds. The document includes a number of examples of current market surveillance practices in different industrial sectors where governments have decided to intervene in the market. Where intergovernmental, governmental or global resources exist, these can be of assistance to those less developed countries, or countries with less developed market surveillance activities. Many of these sectors are complex and require specific characteristics to be present in the market surveillance systems that apply to them, and these are considered in detail. Both pre-market assessment and approval systems, and post-market surveillance play a part in achieving the necessary level of protection.

The approach taken has, for practical reasons, to be one in which costs and benefits are weighed. The costs of establishing and maintaining market surveillance activities are a key consideration, and a number of solutions are explored. For sustainability, the funding available to market surveillance authorities needs to keep pace with the demand for their services. This places pressure on governments which have to cope with competing demands on fiscal authorities, especially in times of economic downturn and in the face of natural disasters.

This document recognizes the contribution made by the United Nations Economic Commission for Europe (UNECE) document entitled “Guide to the General Market Surveillance Procedure”

and attempts to highlight regulated areas where those less developed countries can benefit from non-governmental international systems that are already in place without having to reinvent them. This document is not intended to be a “How to” guide, but rather a general introduction to market surveillance good practice. It also highlights the invaluable role that can be played by the correct and consistent

use of the standards and guides in the “CASCO Toolbox”. This suite of International Standards and guides includes authoritative documents in the following fields:

- Principles and common elements of conformity assessment
- Code of good practice for conformity assessment
- Product and system certification

- Inspection, testing and calibration
- Accreditation
- Marks of conformity
- Mutual Recognition Arrangements (MRAs)

Further information on the CASCO Toolbox and other activities of CASCO (ISO committee on conformity assessment) can be obtained at [www.iso.org/casco](http://www.iso.org/casco)

# THE NEED FOR MARKET SURVEILLANCE

When products are traded between willing suppliers and willing consumers within a free market system where there are no price controls, the “laws” of supply and demand usually take precedence. Suppliers have an interest in efficiently providing as many products as possible, in order to remain in business and grow. Consumers, on the other hand, have a need to buy products, but seek to obtain them at the best price possible. Somewhere in the negotiations that follow, the issue of product quality comes up. Consumers require a level of quality that equates to at least their perception of fitness for purpose and safety, or else they will not buy the product. It is, of course, in the interest of suppliers to meet the requirements of consumers

so as to guarantee repeat business. The answer to the definition of that level of fitness for purpose and safety is usually provided by standards.

The situation in practice is not always so simple, however. Firstly, competition in the market leads to new suppliers coming in, offering ever decreasing prices. Secondly, the normal product life cycle results in affluent early adopters paying the most, and late adopters reaping the rewards of economies of scale achieved by the most efficient suppliers, and of lower prices brought about by increased competition. All of this would be manageable if all products conformed to up-to-date standards that address all the safety aspects of a product, all suppliers were

honourable and efficient, and all consumers were knowledgeable – but they are not! Frequently, consumers need to purchase a product about which they cannot be expected to have the same level of technical knowledge as the manufacturer, and they have to buy on the basis of trust. Occasionally, suppliers come to the market with products that do not meet the expectations of the consumer, or are downright dangerous.

In some countries, consumer organizations do not enjoy the adequate level of recognition nor do they obtain an adequate level of financial support. The conformity assessment infrastructure is often lacking, and fewer mechanisms exist for the registering of product-related complaints. As a consequence, products that are quickly recalled in some countries might continue to be allowed on the market in other countries or worse, can be dumped onto their markets because of, amongst other things, a lack of a credible market surveillance system.

When products are involved that can have an effect on health or safety, or the environment, or that might encourage deceptive practices, consumers need protection from faulty or dangerous products or from the unscrupulous behaviour of suppliers. This is where governments need



to step in and introduce legislation in the form of technical regulations to assure a reasonable level of protection. Without some form of enforcement of these regulations, there will be little compliance and, therefore, governments need to establish one or more technical regulatory systems.

A generic technical regulatory system consists of five elements :

- A regulator, in the form of a public body identified to administer technical regulations
- A suite of technical regulations, that normally include both administrative and technical provisions
- A supplier of the product (designer, manufacturer, importer, distributor, retailer) which is responsible for marketing safe products and monitoring their products in the marketplace
- A conformity assessment infrastructure, to enable the regulator to make decisions about compliance or non-compliance, and
- A range of sanctions that can be applied by the regulator in the event of proven noncompliance

Regulators and suppliers have the duty to monitor products coming onto the market to ensure that they conform to relevant technical regulations. This

is the essence of market surveillance, and is either carried out by the regulator itself, or by a market surveillance authority appointed by it. Market surveillance may be carried out before or after the product is placed on the market. For those products that are produced within their own territory, regulators have available to them a variety of approaches, including carrying out inspections, the sampling and testing of products and others. They need to work closely with manufacturers and suppliers, and may take samples from production runs, or even test pre-production prototypes, as part of their duties. They typically carry out both scheduled and random visits to premises, and can obtain and test samples of products already placed on the market, from retail outlets, etc. There are also market surveillance systems where suppliers are obliged to monitor the market and report defects and incidents with products.

Both pre-market and post-market surveillance activities are useful to protect consumer safety and ensure product quality. Proper pre-market surveillance can help ensure the conformity of products entering the market and alleviate the pressure on post-market surveillance. The manufacturer or supplier has liability for any nonconforming product.

With products imported from other countries, although the

applicable technical regulations do not change, regulators in an importing country can use pre-shipment inspection as a tool to prevent nonconforming products entering the market, and have to work in close cooperation with customs authorities.

Regulators or market surveillance authorities also become involved in the investigation of incidents that are notified to them, and that might involve nonconforming products, including the follow-up of any corrective actions. They have a duty, together with suppliers, to keep the public informed of dangers as they arise. The emphasis should not just be on punishing those economic operators who break the rules, but in providing information to them to enable corrective actions to be taken in order to ensure future compliance.

In addition, the communication of identified risks, actions of regulators (including follow-up of any corrective actions required), product recalls, etc., also plays a large part in ensuring the protection of the consumer, and can be lacking in some developing countries.

A number of good practice criteria can be identified that apply to all market surveillance authorities in all regions of the world, and these are discussed next.

# GOOD PRACTICE CRITERIA

Note: The good practice criteria that follow are equally applicable to market surveillance in developed as well as developing countries. In addition to the good practice criteria listed in this chapter, a number of sector-specific criteria apply, and where these apply, they are given in the chapter “Sectorial examples of good practice” on page 25.

## Sound regulatory principles

This section would be incomplete if not prefaced with a broad overview of sound regulatory principles. In the UK, a report (“The Hampton Report”) was published in 2005 for the Better Regulation Executive of the Department for Business Enterprise and Regulatory Reform, entitled “Reducing Administrative Burdens: Effective Inspection and Enforcement” (Philip Hampton, March 2005). This led to the development by that Department of the “Regulators’ Compliance Code – Statutory Code of Practice for Regulators” (Crown Copyright 17 December 2007). The following extracts, known as “The Hampton Principles”, are reproduced with permission from the Better Regulation Executive:

- Economic progress: *Regulators should recognize that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection*

- Risk assessment: *Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources in the areas that need them most*
- Advice and guidance: *Regulators should provide authoritative, accessible advice easily and cheaply*
- Inspections and other visits: *No inspection should take place without a reason*
- Information requirements: *Businesses should not have to give unnecessary information or give the same piece of information twice*
- Compliance and enforcement actions: *The few businesses that persistently break regulations should be identified and face proportionate and meaningful sanctions*
- Accountability: *Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take*

The above principles should form the basis for all regulatory actions, whether in developed or developing countries.

The results of market surveillance activities should be communicated to those who are expected to take actions if necessary.

## Prerequisites for good practice

- a) Empowering legislation for the market surveillance authority/ies must be in place.

Governments have the right to introduce technical regulations in the interests of protecting consumers from the effects of faulty or unsafe products, deceptive practices, counterfeit goods, etc. In doing so, it is implicit that the authorities they establish or appoint to take the responsibility for market surveillance be formally identified, be competent, notified to the public in legislation, and be granted the necessary powers to perform their functions, according to the good practice criteria as listed in this section. For example, powers to enter premises or conduct searches at borders (whether on an *ad hoc* or regular basis), take samples, demand product safety files or other information, recall or confiscate and, where necessary, dispose of nonconforming goods, order a halt to production, delay or prevent market entry or, in extreme cases, even close down premises, need to be detailed and need to be complete.

There are numerous cases of market surveillance authorities labouring under outdated and incomplete legislation, one example being where they

have been given the power to confiscate goods but, by oversight, not the power to dispose of them. The result can be the unavoidable and costly storage of nonconforming goods for an indefinite period while the legislation is amended (and to do so retrospectively can bring its own problems).

Enforceable technical regulations and supporting legislation must exist.

Whereas standards are by definition normative documents with which compliance is voluntary, technical regulations are mandatory. Market surveillance activities in the public interest need a legal basis for their existence and effective implementation and should, therefore, be supported by:

- Technical regulations that are developed in an open and transparent manner, that provide a measured, risk-based and proportionate solution to a real or potential problem. They should consist of technical, preferably performance-based provisions that meet the regulatory purpose, together with administrative provisions that detail their mode of implementation
- General product safety legislation
- Product liability legislation (although this can become a controversial issue and whether this is enacted will

depend to a great extent on government policy, legal systems, etc.)

- Reference to consumer protection and consumer protection legislation – if it exists in the country

**b) Transparency in identifying the authorities responsible for enforcing each technical regulation is essential.**

In some countries, the administration of a wide range of technical regulations is centralized in a single body; in others, there are a wide variety of government departments and other regulators, each with their own set of responsibilities. In one or two extreme cases, government departments have been known to fight “turf wars” over which one of them is legally responsible for market surveillance in a particular field, and this is of course to the detriment of a clear and efficient regulatory system. Often the administration of food and agriculture-related technical regulations is handled separately from non-food regulations, typically by the relevant government ministry or department. In many cases, the responsibility for the regulation of medical devices rests with the relevant department of health. Whatever the arrangements, organized industry, commerce and the public have a right to full transparency in the regulatory systems they have to work under, and consumers

will only draw real benefits and protection from a system where this is in place. Governments, therefore, have a responsibility to organize their regulatory enforcement agencies in such a way as to minimize conflicts of interest and avoid duplication of responsibilities.

**c) Affected parties need to have the right to challenge decisions or actions taken by market surveillance authorities.**

Market surveillance authorities must be accountable for their actions, and need to be able to demonstrate that their work is carried out independently of any other interested party, with complete impartiality and in a non-discriminatory manner, especially between locally manufactured and imported products. Any decision or action taken by an authority during market surveillance activities, therefore, has to be open to legal challenge through the courts. Removal of products from the market, when there is sufficient evidence that a risk exists, should not be delayed waiting for a court decision. The right of appeal should be detailed in the empowering legislation, and in order for it to be effective, each market surveillance authority must be registered as a legal entity (juristic person) in each country in which it operates, in order that it may sue and be sued.

**d) Regulatory interventions must be made at the appropriate**



### **risk-points within the product life cycle.**

An early decision in regulating safety-critical products is where and when to apply the regulations, as product usage and the associated risks differ. For example, with a single-use medical device that is sterile-packed, there might be a need to inspect the product during the production process. But the last point at which inspection of the physical product would be meaningful, would be at the final point of sale. This is because the risk of deterioration of the product after sale is much lower than the risk posed by a nonconforming product leaving the factory gates.

Of course, in the above example, and depending on the product, documentary or physical checks might additionally be required to ensure that product expiry or “use by” dates are not exceeded, stock is rotated and single-use products are only in practice used once and then disposed of, but the product itself would not be likely to require further physical checking after being sold to the end user.

This is in sharp contrast with, for example, some items of personal protective equipment such as breathing apparatus and respirators that are designed for repeated use, and where the end user has a role to play in the safe use of the product. In such a case, depending on the

situation, it might well be appropriate for surveillance to extend to the premises and operations of the end user. This may also be part of other legislation (often contained in labour laws, occupational health and safety legislation, etc.).

It is, therefore, extremely important that the technical requirements for the products being regulated, which may and in many cases are included in standards, be drafted in a manner that facilitates the risk-based needs and objectives of the regulator. This, of course, is best achieved by having close cooperation between the standards developers and the regulators throughout the development process of the standard.



## General good practice criteria

There are many examples throughout the world of good market surveillance practice. The following is not an exhaustive list, but identification of some of the most important criteria.

**a)** Market surveillance authorities should ensure that products covered by technical regulations (even when used, installed and maintained properly) which might compromise the health and safety of users, can be either withdrawn, prohibited or restricted, and the public informed accordingly.

**b)** National market surveillance infrastructures and programmes should ensure effective measures can be taken in relation to any product that is subject to technical regulation within the territory covered by them. Consideration should be given to establishing a national contact point for market surveillance and enforcement of technical regulations.

**c)** Governments should ensure that, by publication in official journals or other, the public is aware of the existence, responsibilities and identity of national market surveillance authorities and of how those authorities may be contacted.

**d)** Appropriate communication and coordination mechanisms should be established between national market surveillance authorities and their counterparts

within the broader geographical region in which they operate.

**e)** Market surveillance authorities should establish adequate procedures in order to :

- Follow up on complaints or reports on issues relating to risks arising in connection with products that are the subject of a technical regulation
- Monitor accidents and harm to health which are suspected to have been caused by those products
- Verify that corrective action has been taken
- Follow up scientific and technical knowledge concerning safety issues
- When there is more than one regulator involved for the same product, there should be procedures to ensure the consistency of their surveillance activities, and ensure the sharing of surveillance information to avoid duplicated sanctions.
- When product recall is involved, 100 % recall should be ensured

**f)** Governments should entrust market surveillance authorities with the powers, resources, skills and knowledge necessary for the proper performance of their tasks.

**g)** Market surveillance authorities should exercise their powers in accordance with the principle of proportionality, in the sense that no intervention should be taken at a level in excess of that required to achieve the legitimate regulatory purpose. Any measure taken to prohibit or restrict a product's being made available on the market or to recall it, is therefore required to state the exact grounds on which the measure is based.

**h)** Governments should establish, implement and periodically update their market surveillance programmes, which should be either general in nature or sector-specific, within the limits of their resources.

**i)** Such programmes should be made available to the public (by way of electronic communication and, where appropriate, by other means).

**j)** Governments and market surveillance authorities should periodically review and assess the functioning of their market surveillance activities, both from an effectiveness and from a cost/benefit perspective.

**k)** The results of such reviews should be made available.

**l)** Government and regulators should provide adequate training to all those involved in surveillance activities including technical regulations and surveillance procedures.

m) Surveillance activities can be triggered in a number of different ways :

- Routine surveillance mandated by the regulator
- Complaints about a product that is subject to regulation
- As a result of quality or safety failures
- Information received from other regulators in other countries or other parties
- Other evidence of increased risk associated with a product subject to technical regulation

## Market surveillance methodology

Note: The United Nations Economic Commission for Europe (UNECE) which also uses standards is preparing a guidance document on a General Market Surveillance Procedure that will include detailed flow-charts of the steps in the process. The general principles in this section are in alignment with those steps.

a) Market surveillance authorities should perform appropriate checks on the characteristics of products to an adequate level to achieve the regulatory purpose, by means of documentary checks and, where appropriate, physical and laboratory testing on the basis of adequate samples. When doing so, they should take account of established principles of risk assessment, complaints and other information.

b) Market surveillance authorities should require economic operators to make available such documentation and information as appear to them to be necessary for the purpose of carrying out their activities and, where it is deemed necessary and justified, should enter the premises of economic operators and take the necessary samples of products for examination or testing. After investigation and confirmation that the product is unsafe or unfit for use, they may destroy or otherwise render inoperable products that present a serious risk where they deem it necessary.

c) Market surveillance authorities should consider the use of services of accredited, independent and impartial third-party conformity assessment bodies where these exist. Conflicts of interest between market surveillance authorities and test

laboratories should be avoided wherever possible.

d) Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities should take due account of such reports or certificates provided that the accreditation body is signatory to the mutual/multilateral recognition arrangement of ILAC or IAF, whichever is applicable.

Note 1: In this regard, accreditation of inspection bodies or test laboratories to relevant International Standards such as ISO/IEC 17020 and ISO/IEC 17025 plays a major role in assuring general levels of competence. Accreditation of certification bodies to ISO/IEC 17065 or ISO/IEC 17021, as relevant, is similarly valuable.

Note 2: Where necessary and appropriate, the regulator should make arrangements with third-party testing and inspection bodies on the use and disclosure of testing and inspection results so as to ensure confidentiality.



e) Market surveillance authorities should take appropriate measures to alert users within their area(s) of jurisdiction, within an adequate timeframe, of hazards they have identified relating to any product so as to reduce the risk of injury or other damage. In this context, a national website on which unsafe and withdrawn or recalled products are listed, is of great use. However, this can be achieved by using radio, television and printed media where these are more commonly used.

f) Market surveillance authorities should cooperate as necessary with economic operators regarding preventive or corrective actions that could prevent or reduce risks caused by products made available by those operators.

g) Where a market surveillance authority decides to withdraw a product that has been manufactured in another country outside its area of jurisdiction, it should inform the local representative of the economic operator or importer concerned at the address indicated on the product in question, or in the documentation accompanying the product.

h) Market surveillance authorities should carry out their duties independently, impartially and without bias. Operating procedures should exist that require this, and corrective action should be taken in cases where such procedures are not followed. A general code of good conduct for

inspectors, coupled with standard operating procedures for the processes of sampling, inspection, conformity assessment and the initiation of corrective action, are also required. ISO/IEC 17024 provides information on the certification of persons and may be of value in this case.

i) Market surveillance authorities should observe confidentiality, where necessary, in order to protect commercial secrets or to preserve personal data, subject to the requirement that information be made public to the fullest extent necessary in order to protect the interests of users.

j) Market surveillance authorities should ensure that products which present a serious immediate or latent risk that requires rapid intervention, be recalled, withdrawn, or prohibited from sale on the open market, and that the public be informed without delay.

k) In relation to (j) above, the decision as to whether or not a product represents a serious risk should be based on an appropriate risk assessment that takes account of the nature of the hazard and the likelihood of its occurrence after due consideration taken of the level of awareness and understanding of the hazards by persons using the product. In some developing countries, there could be cases where products could pose a particular hazard, e.g. electrical showers, kerosene stoves, etc.

The feasibility of obtaining higher levels of safety or the availability of other products that present a lesser degree of risk should not constitute grounds for considering that a product presents a serious risk.

l) In the collection of data from the marketplace, market surveillance authorities should ensure they have sufficient expertise to conduct meaningful evaluation of those data and to assess risks therefrom.

m) Market surveillance authorities should, to the greatest extent possible, cooperate with and attempt to harmonize their procedures with those of their counterparts in other countries.

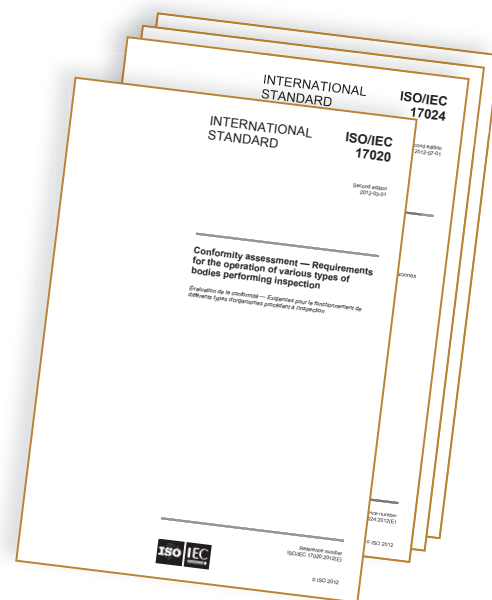
Where the regulator conducts routine market surveillance, it should take into consideration the available conformity assessment systems that are established and implemented in the various areas and then determine the products that should be focused on, and associated surveillance methods. Regulators should determine how to use the existing conformity assessment systems to assist them and reduce costs associated with market surveillance. In this regard, regulators should require conformity assessment bodies to ensure products tested or certified by them continuously conform to specified requirements in standards or technical regulations.

## The CASCO Toolbox

The latest editions of the International Standards and other guidance documents in **Table 1** below are developed by CASCO and are joint publications<sup>1)</sup> by ISO and IEC. They should form the basis for market surveillance and its related activities :

It is recommended that regulators and market surveillance authorities use these standards and guides with no changes. They may have a need for additional requirements based on local conditions.

1) Designations correct as at May 2012.



**Table 1 – List of ISO/CASCO standards and guides**

Reference	Title
ISO/IEC Guide 23	Methods of indicating conformity with standards for third-party certification systems
ISO Guide 27	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
ISO/IEC Guide 28	Conformity assessment – Guidance on a third-party certification system for products
ISO/IEC Guide 53	Conformity assessment – Guidance on the use of an organization's quality management system in product certification
ISO/IEC Guide 60	Conformity assessment – Code of good practice
ISO/IEC 17065	Conformity assessment – Requirements for bodies certifying products, processes and services.
ISO/IEC Guide 67 (under revision as ISO/IEC 17067)	Conformity assessment – Fundamentals of product certification
ISO/IEC Guide 68	Arrangements for the recognition and acceptance of conformity assessment results
ISO/IEC 17000	Conformity assessment – Vocabulary and general principles
ISO/IEC 17007	Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment
ISO/IEC 17011	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021	Conformity assessment – Requirements for bodies providing audit and certification of management systems
ISO/IEC 17024	Conformity assessment – General requirements for bodies operating certification of persons
ISO/IEC TS 17022	Conformity assessment – Requirements and recommendations for content of a third-party audit report on management systems
ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17030	Conformity assessment – General requirements for third-party marks of conformity
ISO/IEC 17040	Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies
ISO/IEC 17043	Conformity assessment – General requirements for proficiency testing
ISO/IEC 17050-1	Conformity assessment – Supplier's declaration of conformity – Part 1 : General requirements
ISO/IEC 17050-2	Conformity assessment – Supplier's declaration of conformity – Part 2 : Supporting documentation

# RESOURCES, COSTS AND BENEFITS

In a developing country context, the considerations to take into account when establishing or maintaining a regulatory/market surveillance authority can be even more complex than in a developed country. The necessity to protect the population from unsafe products is just as pressing and valid as it is in developed countries, but additional needs and costs are often exacerbated. When items are imported and are health- and safety-critical items, the market surveillance “balance” is tipped very much towards the control of imports at borders rather than surveillance of items leaving the factory gates.

Some countries can be the recipients of substandard or counterfeit products, and in the absence of alternative imports, the population often has no choice but to buy these products when they find their way into the domestic market. The choice for the end consumer, therefore, can come down to take poor quality and potentially unsafe products or none at all. A culture of quality and safety is often not well recognized, and consumers consequently also have little voice with which to alert their governments to regulatory needs.

In developing and developed countries where there is little evidence of the existence of a



national policy or framework within which different regulatory bodies can exist, the regulatory systems that are in place are fragmented and present an inconsistent approach.

Governments are, nevertheless, faced with huge responsibilities to protect the health and safety of citizens while, at the same time, facing competing demands to alleviate food shortages, recover from natural disasters, etc. It is also highly likely that a newly-established market surveillance authority will not be able to become self-sustaining for some time. It will require guaranteed budget support, partly due to high entry costs, relatively low

volumes of goods that need to be monitored and, especially, often due to the inability of local industry to meet the cost burden of market surveillance, whether through levies or increases in other taxes, without pricing their products too high to be able to maintain market share against cheaper imports.

In addition, suitably accredited conformity assessment providers are often unavailable within the national territory, which means that some tests have to be outsourced to higher cost laboratories overseas. There is often insufficient “critical mass” for the testing business in a country for a viable conformity assessment operation to be established.

The costs facing market surveillance authorities include normal set-up costs, but also involve high staffing costs (as the market for the relatively few people with qualifications is often very fluid), high costs of training, study visits, sampling, inspection and testing. High communication costs with stakeholders in large, sparsely populated geographical areas, as well as the capital cost of obtaining modern information and communication technology, pose further barriers to entry. But market surveillance authorities have to be able to afford to use the services of adequate, preferably accredited conformity assessment bodies from day one, and to carry the financial burden of providing their operations for several years before any pay-back can be expected. Where governments have decided to make market surveillance activities either self-funding or partially self-funding, they might need to

provide some “seed money” and to nurture the new market surveillance authority until the volume of work and, therefore, income reach a level of sustainability.

One solution often taken for practical reasons is to base the regulatory/market surveillance function within an already established conformity assessment or national standards body. Some testing facilities might exist, some of which might be accredited, and the standards development function can be used to assist in preparing technical regulations. This model understandably attracts criticism for being a mix of interlinked functions that should, according to best practice criteria, operate independently of each other. The tendency then can be for large developed economic trading blocs, when negotiating economic partnership agreements with a developing country, to

insist as a prerequisite that these incompatible functions be separated from each other. This can have negative repercussions for a country’s infrastructure at a time when the country’s economy has a chance to expand. Whatever the final solution in cases like this, some costly trade-offs usually have to be made.

In deciding which regulatory sectors to target, governments face a dilemma. If they spread the available resources too thinly, the risk is that a small and insignificant intervention will be made in a large number of areas and, therefore, the regulatory purpose has no chance of being achieved. On the other hand, to concentrate all resources in one or two of a number of high risk areas, means that the neglected areas continue to present health and safety hazards. The hard fact is that in such cases the only viable option is to concentrate available resources on those areas that pose the highest risks, and to have a suitable long-term plan.

The choice of methods of intervention used in market surveillance will also affect costs, and in the absence of 100 % sampling, inspection and testing will also affect the residual risk of noncompliance.

Reliable pre-shipment inspection of imports can reduce the risk of noncompliance, but comes



at a significant cost, whereas at the other end of the scale, pure reliance of first party (supplier's) declaration of conformity is highly cost-effective, but may give little assurance of compliance in the absence of additional monitoring and adequate and enforced product liability legislation. Recognizable and traceable marks of conformity from overseas suppliers – information from voluntary conformity assessment sources – product certificates – traceable certificates of conformance – traceable certificates of analysis, could also be of benefit to the local regulator.

Similarly, if a cost/risk analysis is applied to different post-market surveillance options, an interesting pattern emerges. On the one hand, the option to do nothing and await complaints is, of course, the cheapest, but carries a high risk, and it can be argued that this does not constitute market surveillance at all! On the other hand, inspection on a batch-by-batch basis gives a high degree of assurance of compliance, but comes at a high cost. Both of these scenarios are open to debate, and will depend on a number of factors.

Ultimately, the question of who has to pay for the costs of market

surveillance offers few easy answers. Central government is the first and most likely source of funding. But in many developing countries, the treasury is always under strain owing to the demands of other priority areas such as housing and feeding the population, recovering from natural disasters, etc. Thus, even though protection of the population is highly important, it might not receive the level of funding it merits. One model that has found favour in South Africa is a system based around a series of about 80 “compulsory specifications” that are developed with the assistance of the national standards body, but only published as technical regulations under the auspices of the parent government department. A regulator is appointed for the areas covered by the compulsory specifications, and funds its operations by means of a levy raised on the suppliers or importers of affected products. This is an efficient method of collecting funds, but suffers from the criticism that the levy is raised on all operators, not just on those who are failing to comply with the regulations. Even with this model, levies cannot easily be collected until a year or more of market surveillance has taken place, and there is thus a funding gap, at least initially, that

has to be supported by central government.

An alternative method of covering costs would be to build the cost of market surveillance into pre-approval or licensing fees, but as with the levy system, this method of funding can attract criticism from the regulated law-abiding members of industry, who feel they are being double-charged and that the law-breakers are escaping relatively unscathed.

If a market surveillance authority were to take the decision to rely solely on certification as its means of monitoring, the cost would be relatively low. It might even be possible to extract some sort of “recognition fee” from the chosen and approved certifiers, but this method is not the best model and has probably not been seen to work well in practice anywhere. Moreover, it could be seen as a corrupted practice.

The market surveillance authority could also collaborate with recognized and, preferably, accredited third-party product certification schemes. Although not replacing the regulator, this could at least add a degree of confidence to the process.



# PRIORITIZING

It can be argued that all technical regulations inhibit trade to a certain degree, as their purpose is to prevent trade in products that are shown to be harmful. Therefore, the benefits, even of well-administered technical regulations, always have to be weighed against the costs.

On the one hand, technical regulations imposed to protect the community can achieve a high level of compliance, because they are backed by the force of law. They level the playing field and can, in some cases, unintentionally favour local industry versus imports, which can be either a good or a bad side effect depending on the circumstances.

On the other hand, there is typically quite a high cost of compliance, and large businesses, whether local or overseas, tend to be better able to absorb these costs. Trade barriers can easily be created, and if the technical regulations do not keep pace with the state of the art, they can easily stifle competition and break the cycle of innovation.

Regulators need to temper their interventions in the market with a dose of reality. Only those aspects that are really necessary to achieve the regulatory objectives should, therefore, be regulated. While it is good practice to base the technical requirements of such regulations

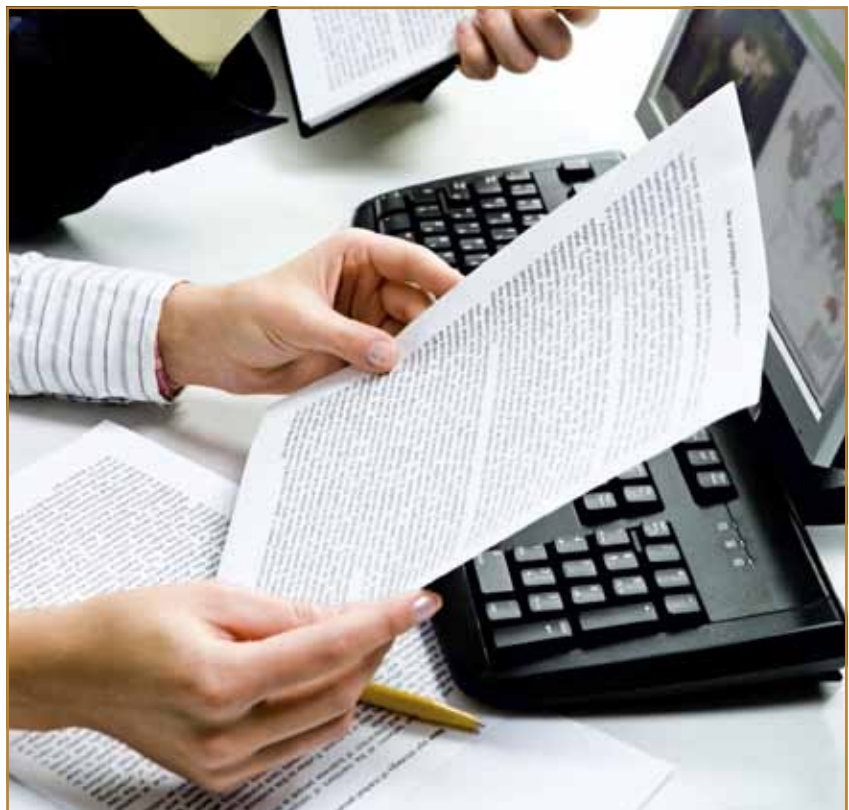
on International Standards, it is important to limit the requirements that are called up into regulation. These should be limited to those that have a bearing on the subject of the regulation (for example, health, safety and environmental requirements should be included, but other performance requirements with no impact on, or relation to, safety should be considered for exclusion).

To ensure that the benefits of any proposed regulation really do outweigh the costs, it is essential that impact assessments be carried out to determine the effect on industry and, in some cases, on the macro-economy. Impacts

should be reviewed periodically and the technical regulations, and therefore their enforcement, should be amended as necessary, or even withdrawn if the regulatory need has fallen away.

The use of standards as the basis for technical regulations is, therefore, highly efficient, as all of these aspects would automatically be considered during the standard development and review process.

The industry sectors that are regulated need to be decided upon and prioritized. The involvement and cooperation of these sectors is invaluable in the structure of a regulatory process. In



some developing countries, the standards base is effectively a collection of de facto technical regulations, as economic players can only in practice sell their goods if they conform to the national standards. This can lead to confusion in the market between standards and technical regulations. Standards are voluntary instruments, whereas only those standards, or parts of them, that serve a real regulatory need, should find their way into regulation. What is required is a limited set of technical regulations where there has been shown to be a genuine regulatory need due to a breakdown in the normal market forces of supply and demand.

One possible solution for developing countries is to participate in regional organizations that concern themselves with the harmonization of standards, that base national or regional standards on International Standards, wherever possible, and that therefore harmonize the effect

of all technical regulations based on them. Free trade areas are of great importance in this regard, since the presumption of conformity and free passage of goods within the area, once a product has legally entered one of its member countries, reduces the administrative and cost burdens on national structures. There is, of course, a trade-off in terms of risk and trust between member countries.

Some of the benefits of basing technical regulations on standards include the fact that they readily provide a quality/performance baseline. They can promote fair competition and efficiency, they are always easy to update to reflect advances in technology, and when the underlying standards are international, harmonization is facilitated between countries and regions. Standards can, however, be manipulated to entrench technologies and can “lock in” outmoded systems if not kept up to date. For this reason, the

truly International Standards developed by ISO and the IEC are preferred, as the international consensus they require prevents these unwanted side effects.

When it comes to regulatory policy, some policy makers do not understand that there will always be a gap between the low, or zero level of risk they might be aiming for, and the level that is achievable in practice through regulation. Resource constraints and cost-benefit calculations will dictate that some trade-offs will always be required.

Even in most developed countries, regulation is only carried out in a limited number of technical areas – details are available from the WTO enquiry points and government websites. It is recommended that countries should not consider imposing regulations and undertaking market surveillance in additional areas unless specific risks have been identified in their own markets.

# NATIONAL, REGIONAL AND GLOBAL ISSUES

Regulatory authorities in the developing world tend to exist only on a national basis. Although a number of free trade areas exist where, in theory if not always in practice, products that have entered the free trade area legally should be able to cross internal borders without any further involvement of regulators, and a degree of cooperation and information sharing between national regulators is evident. Nevertheless, much more can and should be done within established geographical regions to enhance the benefits of regulatory cooperation.

In a developing region, there are also some synergies to be achieved; for example, an accredited test facility for a given type of product might only exist in one country within a region. Provided there is sufficient trust and cooperation between countries, the use

of each other's facilities, and even of accreditation bodies, provides a way forward. In the Southern African Development Community (SADC) of 15 member states, only two have national accreditation bodies, and the solution that is being applied currently involves the creation of a regional accreditation resource (SADCAS) that can service customers in all member states.

Some challenges to full regional cooperation are likely to exist for a long time, however. Recognition of prior testing in neighbouring member states of a region requires a level of confidence and a certain degree of trust. Levels of regulation and surveillance are likely to differ greatly between neighbours in the absence of full coordination of their activities. The scarcity of accredited test facilities in some developing regions is always a problem, as

are some unexpected challenges such as customs regulations that impede the movement of test samples or calibration materials between countries. Access to inspectors from another member state requires coordination, which is sometimes lacking.

One area of major promise, though, is the opportunity to establish "alert" or information sharing systems that highlight the appearance on the market of noncompliant goods.

There are many examples of regional cooperations in the developed and developing regions of the world, such as MERCOSUR (4 South American countries), CARICOM (15 Caribbean countries and dependencies), ASEAN (Association of 10 Southeast Asian Countries). Some examples of regional or large country markets are given below:

## **USA, Canada and Australia:**

Strictly speaking, each of these nations is not a region but may be regarded as a "federally integrated market". Tariff-free movement of goods is permitted between internal states or provinces. The central federal government is responsible for some technical regulation (but by no means all) through appointed agencies, and the states or provinces contribute additional regulations. Within these markets, surveillance levels are well



established, and the penalties for noncompliance are extremely high.

**NAFTA:** The North American Free Trade Area comprises Canada, Mexico and the USA, and bases itself on the WTO GATT, Technical Barriers to Trade (TBT) and the Sanitary and Phytosanitary Measures (SPS) agreements. Within this region, most tariffs have been eliminated, and a committee on standards-related measures is in existence. As a regional regulatory entity, it has a detailed dispute-resolution procedure and works fairly well in most areas, except perhaps in the field of agricultural products, where a number of significant difficulties remain.

**The European Union:** The EU is a single market that ensures the free movement of people, goods, services and capital among its member states. It has established a standardized system of laws that apply to all member states, and uses “EU Directives” to provide a legal definition of requirements for regulated products. The EU product directives have as their principal goal the creation of a single legal environment between the member states that will facilitate regulation and avoid the occurrence of trade barriers between them. The intention is that products can be sold across the EU without having to undergo repeated assessment and approval procedures. In some cases, their



level of technical requirements has been diluted from those that were previously in place in some member states before the EU was created. Nevertheless, they are equivalent to “technical regulations”, and lay down “essential requirements” that regulated products must conform to. Market surveillance is conducted by designated authorities working through suitably qualified “notified bodies”. Compliance with the national standards that adopt the EN standards provides, by definition, a “deemed to satisfy” method of meeting the essential requirements in the directives, although compliance with the standards is not in itself mandatory. Suppliers remain free

to address the directives directly in any method of their choosing, but this is not always particularly easy.

**Asia-Pacific Economic Cooperation (APEC):** APEC has, as a long-term goal, the creation of a single, region-wide Free Trade Area, and is committed to reducing trade barriers without resorting to legally binding obligations between members. Instead, it promotes dialogue and decisions on the basis of consensus, and favours both International Standards and international models for conformity assessment as solutions.

**East African Community (EAC):** The EAC is a regional intergovernmental organization

comprising Kenya, Uganda, Tanzania, Rwanda and Burundi. It is working towards the creation of a customs union, a common market, monetary union and a political federation. There is an East African Standards Committee responsible for developing harmonized East African Standards, and the EAC Council has the right to declare an East African Standard to be compulsory on the grounds of protection of health, safety, the environment or the elimination of deceptive practices. Each partner state is then obliged to appoint a regulatory authority to administer these compulsory standards and, within the region, the partner states are obliged to recognize each other's product certification marks as their own.

The above regional solutions vary greatly in their complexity, degrees of sophistication and general levels of workability, but they do represent valid attempts at solving the regulatory "dilemma" on a regional basis. What is clear, however, is that in developing regions of the world, even with the combined resources of member states, some of the more demanding areas where market surveillance is required cannot be properly addressed without some sort of global approach.

Global agencies that set standards and provide regulatory solutions and support fortunately exist in many areas. In the food

sector, the United Nations' Food and Agriculture Organization (FAO) and the Codex Alimentarius Commission, recognized by the WTO SPS agreement as the developer of food standards, together with the Global Food Safety Initiative (GFSI) are key players, while in the area of medical device regulation, the Global Harmonization Task Force (GHTF) is made up of both the regulated medical device industry and the major national regulators, such as the US Food and Drug Administration (FDA).

Note: The Codex Alimentarius Commission is a body established by the United Nations Food and Agriculture organization and the World Health Organization (WHO).

In the chemical arena, the EU's regulation on chemicals and their safe use – REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) programme is widely recognized and, in pharmaceuticals, WHO and the European Medicines Agency are extremely active.

Electrical and electronic end-product, equipment and component standards are the realm of the International Electrotechnical Commission (IEC), which also runs three systems, IECEE, IECQ and IECEx providing third-party conformity assessment services through their members and relevant schemes.

In the area of toy safety, the EU's toy safety directive and EN 71 standards, the US ASTM toy standard, the South Africa Product Safety Framework, ISO's International Standard on toy safety ISO 8124, are widely used as reference documents. PROSAFE, the Product Safety Enforcement Forum of Europe, the US Product Safety Commission, Health Canada and the Australian Competition & Consumer Commission (ACCC) are very active in the market surveillance of toys.

Regulators in developing countries can access and benefit greatly from the work of the



above-mentioned agencies, and do not need to develop regulations or enforce them in a vacuum.

Two areas of good practice that have been highly developed over the last few years, and that have changed the regulatory scene dramatically, warrant further mention. These are the effect of the EU's "new approach" on technical regulation, and the emergence of the EU's RAPEX system. The ACCC also has a well-established product recall system in operation.

The new legislative framework: The European Community introduced the CE-marking system in 1985, following the advent of the "global approach". Directives that were in existence prior to the global approach and which, therefore, did not allow for CE-marking, were then referred to as "old approach directives", whereas directives that invoked requirements for CE-marking became known as "new approach directives". Some old approach directives remained in force, but the new CE-marking requirements were intended to apply to products that conformed to all applicable directives, at least one of which was required to be a new approach directive.

The free movement of goods through the European single market is a fundamental concept, and the new legislative framework ought to achieve this

by preventing new barriers to trade, and by a process involving mutual recognition and technical harmonization. The essential principles of the new legislative framework are outlined below:

- Legislative harmonization is limited to "essential requirements" that products placed on the European single market are obliged to meet, if they are to benefit from free movement within the market. (A simple example of an essential requirement is that a given product must be safe to use)
- Technical specifications for products that meet the essential requirements set out in applicable directives are expressed in the form of harmonized standards
- As standards are by definition voluntary, their application is not enforced, and manufacturers are entitled to apply other means to meet the requirements, however products that have been manufactured to harmonized standards are presumed to conform to the essential requirements

The idea behind the "new approach" is that conformity to these harmonized standards is a reliable means of guaranteeing protection in terms of the essential requirements. On a national basis, authorities are responsible for market surveillance. To

underpin this system, a reliable conformity assessment infrastructure needs to exist, that:

- Is consistent, and based on appropriate best practice standards
- Involves accreditation and the use of intercomparison techniques to demonstrate competence
- Promotes Mutual Recognition Agreements
- Minimizes differences in approach and capacity between conformity assessment providers in different member states

Implementation of the new approach on a national basis involves the following:

- Member states must take all necessary measures to ensure that only safe products are placed on the market. This implies a responsibility to carry out market surveillance nationally
- While member states are free to adopt additional national protection provisions, these must not require product modifications or vary the basic conditions for placing a product on the market
- Essential requirements are set out in the annexes to the directives, and include all necessary aspects to achieve the objectives of the relevant directives



- Member states are obliged to presume that products bearing the CE-marking comply with all applicable directives, and may not restrict in any way placing the products on the market, unless it can be shown that the CE-marking provisions have been applied incorrectly
- Where a hazard is identified that is not covered by an existing directive, or where for whatever reason, products are found on the market that are unsafe, member states have an obligation to prohibit or restrict the placing on the market of the products, and to inform other member states of the measures taken and the reasons for them
- Before placing a product on the market, a manufacturer is obliged to subject the product to the necessary conformity assessment procedures
- Third-party conformity assessment is carried out

in member states by “notified bodies” that meet certain requirements

- The CE-marking is an attestation that products comply with essential requirements of applicable directives, and member states are required to protect the integrity of the CE-marking system
- New approach directives are “total harmonization” directives, and supersede all corresponding national provisions

The EU’s RAPEX (Rapid Alert System for non-Food Consumer Products): One of the cornerstones of the new legislative framework to technical regulation is that member states are obliged to notify other member states as soon as they take a decision to withdraw, or restrict the placing on the market of a product for safety reasons. This protects the single market by ensuring that a consistent regulatory approach

is taken against nonconforming products. It serves as a deterrent to those who would attempt to place unsafe products on the market, as quick and coordinated detection of nonconformities and follow-up actions across a number of member states can have a huge financial impact on manufacturers producing unsafe products.

RAPEX is a rapid alert system for dangerous consumer products, and operates across the European Union as well as the other European Economic Area (EEA) countries. It is intended to ensure that relevant information about dangerous products identified by one national authority is made available to all other national authorities and to the European Commission. RAPEX was established under Article 12, and in terms of the notification procedure outlined in Article 11, of Directive 2001/95/EC, the General Product Safety Directive (GPSD). Article 12 of the GPSD



requires national authorities to notify the EC and member states, via the RAPEX system, about relevant details of measures taken to prevent or restrict the marketing or use of consumer products that have been found to pose a serious risk to the health or safety of consumers.

RAPEX covers both measures insisted upon by national authorities and voluntary measures taken by manufacturers, their agents or their distributors. Common measures taken include banning the sales of products, withdrawal of a product from

the market, recalling products already sold into the market and the provision of relevant information to consumers. It covers most non-food consumer products. A different alert system (RASFF) is in place for food and feeds, and dedicated systems exist for medical devices and pharmaceutical products.

National authorities detect, either through their own market surveillance procedures or from complaints or notices received from consumers or producers, that dangerous consumer products are on the market and,

after suitable investigation, notify RAPEX through their national contact point. In turn, the RAPEX system notifies all other national contact points. Weekly overviews of RAPEX notifications are published on the RAPEX website. Manufacturers of products are well advised to maintain an awareness of RAPEX notifications, as knowledge of emerging risks can save them unnecessary expense and facilitate better and safer product design before their products reach the market.



# SECTORIAL EXAMPLES OF GOOD PRACTICE

## Electronic and electrical products

**a) General:** Household electrical and electronic products are bought by virtually every consumer on the planet, and even the simplest and commonest of products, such as electric irons, toasters and radio receivers bear a bewildering array of third-party certification marks or suppliers' declarations of conformity. While these are evidence of a highly regulated global industry, the consumer is usually at a loss as to their meaning. Recent research by TUV (Technischer Überwachungs-Verein) in the UK revealed that 73 % of UK consumers believed that the CE-marking on a product signified that it was

safe. It is a fact that a number of unscrupulous manufacturers fail to test their products and apply a false declaration of conformity, hoping to escape detection. Consequently, it is not surprising that hundreds of thousands of products are stopped by customs officials, trading standards officers, or other surveillance authorities for examination each year. It also seems likely that a number of manufacturers simply do not understand the complex rules that apply to their products and issue declarations of conformity in good faith, but on a false basis. It can, therefore, be deduced with a good level of certainty that a large number of nonconforming imported

products must pass through the border controls and enter the market each year. On the other hand, large, responsible manufacturers in this sector usually have a separate department dedicated to ensuring regulatory compliance; this is especially important given that differences in acceptance requirements, however small, affect product entry into different national markets and need to be catered for. Requirements for operating instruction leaflets, and product or package labelling in national languages, are a prime example of this.

Some of the most frequently notified products in this sector include simple items such as lights, electric plugs and extension cord sets. In 2007, approximately 18 % of RAPEX notifications from the EU to a large manufacturing country involved electrical appliances or lighting equipment. In the EU, the most significant directive for such consumer products is the Low Voltage Directive 2006/95/EC (LVD), but there exist other directives, such as

- The Directive on Radio Equipment and Telecommunications Terminal Equipment (R&TTE Directive 1999/5/EC)
- The Electromagnetic Compatibility Directive (EMC Directive 2004/108/EC)



- Directive 2005/32/EC establishing a framework for the setting of ecodesign requirements for energy-using products (EuP Directive)
- Directive 2006/66/EC on Batteries and Accumulators and Waste Batteries and Accumulators (Batteries Directive)
- Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE Directive)

If an electrical product fails to fall under one of the above directives, it is unlikely to escape the General Product Safety Directive 2001/95/EC (GPSD). There are other directives and regulations that apply in specific circumstances. Similar sets of regulations apply in other developed markets.

The intention of all these directives and regulations is to protect the user or consumer from risks such as electric shock, fire or overheating, explosion or mechanical risks associated with the use of these products.

They are also intended to prevent electromagnetic interference (EMI) caused by their use, by assuring the requisite level of electromagnetic compatibility (EMC) between items of equipment that are intended to operate together. In general, where the risk is deemed to be low, a Supplier's Declaration of

Conformity (SDoC) might suffice, but for higher assessed risks, a third-party product assessment coupled with a quality system might be required. Similar levels of regulation exist in other jurisdictions.

Under the LVD, market surveillance is a requirement that cannot be escaped. A market surveillance activity can be triggered by:

- A registered complaint
- An accident involving the product
- A notification from another member state under the RAPEX system
- A random inspection, or
- A special project, such as Christmas lighting chains

Statistics from Denmark indicate that 52 % of all fires are caused by household appliances, radios, televisions and computers, with another 12 % being caused by luminaires. Reasons for these fires include:

- Misuse of apparatus (hence the need for better instructions): **26 %**
- Faulty insulation: **10 %**
- Use of old apparatus: **10 %** and
- Loose electrical connections: **7 %**

It seems clear that many of these incidents might be avoided by better adherence to standards, in some cases better standards, and in all cases more market surveillance. However, there is always a trade-off between the level of risk that the consumer is willing to accept (often zero) and that which is practically possible (and this is related to cost). Essentially, the consumer has to bear some of the risk. The consumer has to accept some responsibility for notifying authorities about dangerous products. The consumer also has a duty to become better informed, for example (as a minimum) by reading product instructions before using the product.





**b) The market surveillance procedure:** In the EU, market surveillance is carried out by nationally-appointed “notified bodies”. In the United States, regulators, including “code authorities” responsible for installations, use the services of independent conformity assessment bodies such as Underwriters’ Laboratories (UL). They work together as partners in a system, each using their greatest strengths to achieve a consistent and reliable system. It is instructive to research the huge variety of certification marks used by UL for different products and geographical areas. UL protects the integrity of its certifications by carrying out its own investigations of product incident reports, and by undertaking proactive market surveillance activities on products that bear its mark. However, market surveillance authorities all work in a similar fashion.

Firstly, the market surveillance authority develops a market surveillance programme which specifies which product or product group to target, and then obtains samples of that product, either directly from the supplier, or by purchasing it from a retailer. Customs authorities are also authorized to draw samples from shipments at borders.

Secondly, a technical investigation is undertaken. This can involve merely visual inspection or more detailed tests, depending on the nature of the product and the associated risk factors.

Thirdly, the results of the technical investigation have to be evaluated against the prevailing regulation. In the case of the EU’s LVD, this involves coming to a decision as to whether the product is constructed according to good engineering practice (as it relates to safety), and also

whether it could endanger the safety of persons, domestic animals or property. It is important to realize that it must generally be proven that the product is dangerous before any action is taken. It is not sufficient to merely prove that the product fails to conform to a standard.

Fourthly, if a product is found to be dangerous, then the market surveillance authority needs to decide on what actions to take. These can vary, depending on the severity of the case, from relatively minor measures to a complete ban on the further sale of the products and the enforced recall of products already in the market. To achieve a full product recall might involve sending out notices to dealers, newspaper or television advertising, or any other means warranted by the risk.

Finally, it is good practice to notify other countries in some formal manner as to the detailed description of the product and its source, where known, the action taken and the reasons for it.

**c) Market surveillance codes for common deficiencies:** It has to be recognized, when conducting technical investigations of products in this area, that some defects are more important and are evidence of a greater level of risk than others. It is common therefore, when inspecting a product, for the inspection agency to refer to a list of common “codes” for the most



frequently encountered defects. As an example, a relatively minor error found in the technical documentation accompanying a product might be allocated a level 1 code (often known as a “remark”), whereas the absence of operating instructions in the national language of the country in which the product is marketed has to be treated more seriously, and would be allocated a level 2 code (known as a “criticism”). Serious defects that directly affect the safety of the product, such as the existence of accessible live parts when the product is in normal use, would be classified as level 3 (“serious criticism”). The overall assessment of the degree of safety of the product, and the nature of any measures taken in response to defects found, would depend on the nature of those defects as highlighted by their defect codes.

**d) Standards and conformity assessment procedures:**

While there are a number of national standards for products in this category, the vast majority of products are produced to the standards of either the International Electrotechnical Commission (IEC) or CENELEC. In many cases the corresponding IEC and CENELEC standards are technically identical. CENELEC standards are developed with a view to providing a “deemed to satisfy” solution to the requirements of a relevant EU directive. They are adopted by EU member states as their own national standards, and proven conformity to them is deemed to meet the objectives of the directive(s). CENELEC standards are harmonized across the EU, and where no such harmonized standard exists, conformity to the relevant provisions of an International

(IEC) Standard may be presumed to equate to conformity to the safety provisions of the regulations. Where no International Standard exists, proven conformity with a national standard of a member of the EU will be deemed to satisfy the regulations, provided the standard in question does in fact satisfy the objective of the regulation.

Within the EU, suppliers’ declarations of conformity to the relevant directives in the form of the CE-marking are typically encountered. By affixing a CE-marking to the electrical or electronic equipment or even to components, the manufacturer is making a statement that the equipment meets the requirements of all relevant directives. By law, the manufacturer or its agent which places an electrical, or electronic product or component on the single market in the EU, has responsibility for compliance with the CE-marking directives, which can sometimes be complex.

Suppliers’ (or “first party”) declarations of conformity are not the only method of attesting conformity, however. In fact, when a market surveillance authority needs to assess whether a product actually does conform to the relevant directive or other regulation, it usually needs to have inspection and testing carried out by independent third parties. A number of third-party conformity marks are commonly encountered on electrical products

that are centrally manufactured and marketed in many countries; these can easily be seen by inspecting common household appliances or electronic apparatus.

The IEC takes no position on which means of conformity assessment is more acceptable, and recognizes all attestations of conformity, but it does offer a number of conformity assessment systems that have developed into extremely useful tools.

**e) The IEC conformity assessment systems:** Part of the landscape surrounding the marketing of electronic and electrical products revolves around conformity assessment, and how a manufacturer can best find a way through the maze of regulations and requirements. The IEC runs two systems known collectively as the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components, or IECEE.

The two systems are:

◆ **The IECEE CB Scheme:**

In recognition of the need to facilitate international trade in electrical equipment, primarily intended for use in homes, offices, workshops, healthcare facilities and similar locations, for the benefit of consumers, industries, authorities, etc., and to provide convenience for manufacturers and other users of the services provided by various National

Certification Bodies (NCBs), an international scheme is operated by the IECEE (IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components), known as the CB Scheme. The scheme is based on the principle of mutual recognition (reciprocal acceptance) by its members of test results for obtaining certification or approval at national level.

- ◆ The scheme is intended to reduce obstacles to international trade which arise from having to meet different national certification or approval criteria. Participation of the various NCBs within the scheme is intended to facilitate certification or approval according to IEC standards. Where national standards are not yet completely based

on IEC standards, declared national differences will be taken into account; however, successful operation of the scheme presupposes that national standards are reasonably harmonized with the corresponding IEC standards. Use of the scheme to its fullest extent will promote the exchange of information necessary in assisting manufacturers around the world to obtain certification or approval at national level. The operating units of the scheme are the NCBs. These NCBs employ testing laboratories, also accepted according to the rules, known as CB Testing Laboratories (CBTLs)

- ◆ The CB Scheme is based on the use of CB test certificates which provide evidence that representative specimens of the product have successfully



passed tests to show compliance with the requirements of the relevant IEC standard

- ◆ A supplementary report providing evidence of compliance with declared national differences in order to obtain national certification or approval, may also be attached to the CB test report
- ◆ The first step for an NCB, intending to operate in the CB Scheme, is to be accepted as a “recognizing NCB”. Such an NCB is prepared to recognize CB test certificates as a basis for certification or approval at the national level for one or more categories of products
- ◆ The second step for an NCB, which can be taken at the same time as the first step, is to be accepted as an “issuing and recognizing NCB”. Such an NCB is entitled to issue CB test certificates for the categories of equipment for which it recognizes CB test certificates. It should, however, be noted that an NCB may recognize CB test certificates for more categories of equipment than those for which it is entitled to issue CB test certificates.
- ◆ **The IECEE CB-FCS Scheme:** The IECEE (CB) Full Certification Scheme (CB-FCS) is an extension of the international IECEE CB Scheme and is an option



to be exercised by the participants in the CB Scheme and by applicants under the same IECEE management structure. The CB-FCS is a scheme based on the principle of mutual recognition of Conformity Assessment Certificates (CACs) and Conformity Assessment Reports (CARs) by its members. It serves as the basis for approval or certification, at the national level, of products within the scope (see Clause 1 – Scope) to the standards accepted for use in CB-FCS. The scheme is intended to reduce obstacles to international trade that may arise from having to meet different national certification or approval criteria and processes. Participation of the various National Certification Bodies (NCBs) within CB-FCS is intended to facilitate

certification or approval according to IEC standards. Where national standards are not yet completely in line with IEC standards, declared national differences are taken into account; however, successful operation of the scheme presupposes that national standards are reasonably harmonized with the corresponding IEC standards. Use of CB-FCS promotes the exchange of information necessary in assisting manufacturers to obtain certification or approval at a national level in one or multiple countries and regions. Member NCBs to which an applicant (subclause 3.10) applies for a national certification or approval (NCB “B”), accept the conformity assessment certificate and associated conformity assessment report issued

by NCB “A” as a basis for such certification or approval. As an NCB “B”, its national standards shall, as far as possible, be aligned with the IEC and its national certification procedures. It should, as far as possible, be harmonized with these rules of procedure. If, however, differences exist, they are formally declared to the IECEE Secretariat for publication in order that member NCBs are able to properly cover these differences when acting as NCB “A”. CB-FCS is a product certification System 5, as defined in ISO/IEC Guide 67 (subclause 6.3.7, *System 5*)

- ◆ This system includes testing and assessment of the quality system involved. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity. The certification system includes the following:
  - a) Samples requested by the certification body
  - b) Determination of characteristics by testing or assessment
  - c) Initial assessment of the production process or the quality system, as applicable
  - d) Evaluation of the test and assessment reports
  - e) Decision

- f) Licence
- g) Surveillance of the production process or quality system, or both, of the organization
- h) Surveillance by testing or inspection of samples from the factory or the open market, or both

Note 1: The extent to which the three elements of on-going surveillance are conducted may be adjusted for a given situation. As a result, this system provides significant flexibility for on-going surveillance

Note 2: Whether or not the NCB “A” issues its certification mark, it remains responsible for the on-going conformity of the product(s) for which the CAC has been granted

- ◆ CB-FCS includes the following for the NCB “A”:
  - a) Type testing by a laboratory accepted within the CB scheme and issuance of a CAR, and
  - b) Initial factory inspection including evaluation of the factory’s quality management system (QMS)
  - c) Issuance of the CAC
  - d) Follow-up factory inspection by the NCB “A”, that in addition to assessing the product, the manufacturing process and the QMS, will also include re-testing of samples from production, when applicable according to the requirements of the NCB “A” and/or Body “B”. [See (g) and (h) and the Note in the description of ISO System No. 5 above].
- ◆ CB-FCS includes the following for the NCB “B”:

- a) Evaluate the CAC and CAR including, if necessary, direct separate consultation with NCB “A” to verify validity, initial inspection, follow-up inspection, QMS surveillance and completeness of the CAC and CAR
  - b) Test sample(s) are requested only if there are well-founded reasons, e.g. CAC and CAR are not complete or there is a justified technical doubt
  - c) Issue the NCB “B”’s certification/mark/licence according to its normal procedures
  - d) Accept initial factory inspections carried out by NCB “A”
  - e) Accept components integrated in appliances and which have been tested/verified/inspected by NCB “A” and used within their ratings and conditions of use
- A third system exists for certification to standards relating to equipment for use in explosive atmospheres – the IECEx system. This international certification system for specialized products is intended for use in hazardous areas. It offers manufacturers a single test and assessment report for acceptance in all participating countries. It works in a manner similar to that of the CB system, except that for equipment of this nature, the testing and acceptance regime is often extremely complex, and the time taken to achieve national certification is often 12 months or more. Participation in the IECEx

system, as with other systems, can significantly reduce manufacturers' compliance costs and facilitate earlier market entry.

Finally, a separate system for electronic components exists – the IEC Quality Assessment System for Electronic Components (IECQ system). A prerequisite for membership in this system is proven compliance with either ISO 9001 or ISO/IEC 17025, as relevant.

**f) Implications for developing countries:** For manufacturers of electrical and electronic products in developing countries, high capital investment and large-scale production costs, together with regulatory compliance costs, often pose insurmountable barriers to market entry. Once sufficient economies of scale have been realized, however, compliance costs can become more manageable. The temptation to reduce these costs by issuing false suppliers' declarations of conformity without the proper technical dossiers and test reports in place, has to be weighed against the severe financial and often criminal penalties likely to be incurred when nonconforming products are detected. This is becoming more, rather than less, likely as a result of ever more sophisticated notification systems in the larger and more lucrative markets. New manufacturers or product developers are often best advised to use the services of large, well-established contract manufacturers,

so as to take advantage of their established quality control and management, and regulatory compliance systems.

Consumers in developing countries, as in other countries, are often assailed by products that bear large numbers of markings that they deduce, often erroneously, to signify that the products are safe.

National standards bodies and regulatory agencies in these countries have a duty to inform consumers about the risks, and to collaborate, nationally and regionally, in putting together a realistic, workable market surveillance system that leverages, wherever possible, current best practice from the developed world.

## Medical devices

**a) General considerations:** The term “medical devices” covers a wide range of instruments, apparatus and machines of all levels of sophistication used to prevent, diagnose or treat disease.

ISO 14155-1, *Clinical investigation of medical devices for human subjects – Part 1: Requirements*, defines a medical device as: “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used on human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring,

treatment, alleviation or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

It can thus be seen that a single regulatory control mechanism for all medical devices is out of the question, and special rules are needed.

Developing countries tend to not manufacture high-end medical devices, but increasingly the re-usable or single-use low-technology products are starting to appear on the market from suppliers in a number of developing countries in addition to the traditional sources, where controls





have always been fairly strict. Where a country does not have very well-developed regulatory systems for medical devices, it creates a real risk for patients. This is probably a consequence of their importing most medical devices in the past and relying on proof of registration in a major developed country as a surrogate means of pre-market control, but the risk is increasing that the developing world might already be importing large quantities of unacceptable products through a lack of controls. This situation is exacerbated when one considers that in addition to monitoring market entry, the lack of monitoring of medical devices in use, their re-use and their disposal pose additional risks.

Fortunately, since 1992 the Global Harmonization Task Force (GHTF), a voluntary group of representatives from medical device regulatory

agencies and industry, has been working on ways to achieve greater uniformity between national medical device regulatory systems aimed at enhancing patient safety and increasing access to safe, effective, and clinically beneficial medical technologies around the world. Similarly, the World Health Organization (WHO) is extremely active in making information and technical support available to regulators. Both organizations have published a number of extremely useful guides to assist regulators in developing countries who want to develop their systems to higher levels.

Owing to the large variety of medical devices and the nature of their use, pre-market control often involves clinical trials in addition to testing of the finished product. Each medical device needs to be classified into one of a number of classification groups

in order to set the level of monitoring and oversight required.

Typical characteristics of a regulatory regime would include :

- A clear and unambiguous classification scheme
- A pre-market review of the technical documentation relating to the product
- A document that outlines the essential requirements for the product
- A risk management programme that covers the entire product life cycle, including use, re-use and disposal
- A quality management system
- A requirement for the marketing or supplying entity to be registered as such and, therefore, accountable within the jurisdiction of the regulator
- A “vigilance” mechanism for the logging and processing of complaints and the reporting of incidents

While most major manufacturing countries address all these issues, the mechanisms they use still differ. For example, in some countries a three-level classification system is in use, whereas in others there are up to five classifications. The GHTF is working toward resolving these differences and encouraging convergence in regulatory practices, but this will take time. Meanwhile, developing countries need to look for common ground



on which to base their regulatory systems.

**b) Common regulatory practices between major developed countries:**

The following common features of the regulatory systems in the USA, Canada, the European Union and Japan can offer some guidance:

**Use of International Standards:** Where International Standards exist for medical devices intended for global use, they should be (and, in general, are) used. Of particular relevance is ISO/TR 16142, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*. This ISO Technical Report is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes. It is one of a series of international normative documents published by ISO Technical Committee TC 210, *Quality management and corresponding general aspects for medical devices*.

Further details may be obtained from: [www.iso.org/iso/standards\\_development/technical\\_committees/list\\_of\\_iso\\_technical\\_committees/iso\\_technical\\_committee.htm?commid=54892](http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=54892)

**Classification:** All countries use some sort of “rule system” for the classification of medical

devices, and decisions are taken either by an expert panel or by a designated body. The GHTF has produced a generic rule-based system, incorporating a number of “decision trees” that can be used, but full harmonization is yet to be achieved.

**Conformity assessment:** In general, a government agency retains responsibility for the conformity assessment of high-risk products, whereas medium- and low-risk products may be assessed by third parties.

**Essential requirements for products:** All countries give general guidance, but the degree of product-specific guidance varies. This is an area where the harmonization work of the GHTF will bring about big improvements.

**Technical documentation required:** In all countries there is a requirement for documentation,



but the format and specific requirements vary. In general, there is an increase in requirements with increasing risk.

**Labelling requirements:** In all countries there are requirements for labelling, both on the device, where deemed necessary and feasible, and in terms of the descriptive and informational literature that accompanies the device.

**Risk management:** A risk management approach seems to be mandated by law in all jurisdictions. ISO 14971:2007, *Medical devices – Application of risk management to medical devices*, provides guidance in this regard.

**Quality management systems:** The use of the international quality system standard ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, which has many similarities to ISO 9001, is widespread.

**Registration systems:** In all countries there is some sort of “competent authority” nominated to take responsibility for licensing, and foreign manufacturers of medical devices are required to nominate a local agent or representative.

**Vigilance processes:** Incident reporting processes are a fundamental part of the requirements in each country.

**c) The World Health Organization (WHO):** WHO has provided technical support over a

number of years to countries that wished to implement improved medical device regulatory systems. It encourages governments to follow the growing movement towards harmonized regulatory systems, because a proliferation of different national regulations increases costs, hinders access to healthcare technologies and can even unintentionally jeopardize the safety of patients. It encourages countries to adopt, where appropriate, the device approvals emanating from existing advanced regulatory systems, since it recognizes that the regulatory process represents a vast, and often unnecessary, drain on scarce resources, both financial and human. The aim is to allow countries with weak regulatory systems to place the emphasis and initial resources on areas such as vendor and device registration, training, surveillance and information exchange systems on the assessment of the medical devices in use. WHO has published a comprehensive document entitled “Medical device regulations – Global overview and guiding principles”, which is available as a free download from their website [www.who.int](http://www.who.int)

**d) The Global Harmonization Task Force:** In 2000, the GHTF published a number of documents, including:

- The role of standards in the assessment of medical devices

- Review of current requirements on post-market surveillance
- Principles of medical device classification
- Principles of conformity assessment for medical devices
- Essential principles of safety and performance for medical devices

These guideline documents and the on-going work of the GHTF provide a sound basis for developing countries to establish and upgrade their regulatory systems for medical devices. Further information can be obtained from the website [www.ghtf.org](http://www.ghtf.org)

**e) Medical device regulation in the USA:** In the USA, medical device regulation falls under the US Food and Drug Administration, or FDA. The basic regulatory requirements that manufacturers of medical devices intended to be distributed in the USA must comply with are:

- Establishment registration
- Medical device listing
- Pre-market notification (unless exempt), or pre-market approval
- Investigational device exemption for clinical studies
- Quality system regulation

- Labelling requirements, and
- Medical device reporting

Further details are available from [www.fda.gov](http://www.fda.gov)

**f) Medical device regulation in the European Union:** Within the European Union, medical devices are regulated both in terms of the general product safety directive and a number of medical devices directives, which are applicable in all member states. The equivalent in each member state of the FDA in the USA is known as a “competent authority”, and conformity assessment is carried out by a number of “notified bodies”. Other legislation also plays a part, for example in the U.K. the medical devices regulations are also deemed to be safety regulations under the Consumer Protection Act. In order to enforce these regulations, the competent authority has an obligation to ensure that the relevant regulations are complied with, and to ensure that appropriate action is taken to restrict or, where necessary, prohibit unsafe products from entering the market or being put into use.

Within the EU system, suppliers who claim conformity with appropriate directives are obliged to place the CE-marking on their products – thus constituting a supplier’s declaration of conformity. Conformity may, in practice, be established either by showing conformity to relevant (“deemed

to satisfy”) EN standards or by addressing the directives directly, although this latter route is unusual. The duties of the competent authorities, therefore, come down in general terms to:

- Investigating complaints received about CE-marked products
- Carrying out planned and random inspections at the premises of registered suppliers and from the market itself
- Monitoring the work of the notified bodies to obtain information on the degree of compliance of suppliers (especially in regard to high-risk devices)
- Carrying out ad hoc investigations in cases of apparent noncompliance

The emphasis is in the first instance on documentary review and assisting suppliers to comply voluntarily. Inspections are only undertaken where deemed necessary, and drastic action is only taken where there is a clear case of noncompliance and a threat to the health of the consumer. The inspectors have a wide range of powers, including powers of entry into premises and to examine, search and seize records or nonconforming devices. All enforcement actions are designed to be proportionate to the assessed risk, and a wide range of sanctions, accompanied by an appeal system, is

put in place. For all operations carried out by inspectors, standard operating procedures have to be followed.

**g) Implications for developing countries:** WHO states, in an aide-memoire for national medical device administrations, in its document “Medical device regulations – Global overview and guiding principles”:

*“A medical device can range from a simple wooden tongue depressor or stethoscope to the most sophisticated implants or medical imaging devices. In general, a medical device is an instrument, apparatus or machine used to prevent, treat or diagnose disease. It also serves to detect, measure, restore or modify the structure or function*

*of the body for a given health purpose. Typically, a medical device achieves its purpose without entering metabolic pathways.*

*Optimum safety and performance require cooperation among all involved in the life span of a medical device; the government, the manufacturer, the importer/vendor, the user and the public – each has a specific role to play in this risk management.*

*Many countries procure medical devices that may be substandard. Some manufacturers of medical devices may also be unaware of minimum standards. Governments that are unable to carry out pre-market review, either for imported devices or those manufactured locally, could assure regulatory compliance*



*by taking advantage of the work of major device manufacturing countries. A priority in local regulatory development should be the establishment of vendor and product registration.*

*Education and training of users, and the continued assessment of medical devices in use is as important as product control. It is critical to have access to a system for informing and collaborating with the manufacturer, vendor, all users, the public and relevant international organizations of hazards/issues related to medical devices.”*

WHO also recommends collaboration with stakeholders to ensure that national policies on

medical devices are clear and comprehensive, and that the recommendations on global harmonization for regulatory requirements and procedures (such as those issued by the GHTF) be adopted. It makes a plea to national authorities to ensure that classified medical devices are manufactured in conformity with applicable quality system standards (such as ISO 13485), and that links be established to networks that monitor medical devices.

Finally, it encourages national authorities to participate in post-market surveillance and medical device alert issues in order to harmonize the effects, not just

the practice, of global harmonization recommendations.

It should be noted that in the EU the “RAPEX”, or Rapid Alert System for dangerous consumer products, does not cover food, pharmaceutical and medical devices, for which dedicated sector-specific mechanisms are required.

The advice for developing countries is unequivocal – by participating in the harmonization initiatives with respect to medical devices, the time and cost of marketing products can be reduced, regulatory efficiency can be optimized, market access can be facilitated and the health of the public can be protected.

# FOOD AND AGRICULTURAL PRODUCTS

## a) General considerations :

One of the most complex regulatory areas in any country involves actions taken to assure an acceptable level of food safety, whether for human consumption (foods) or for animal consumption (feeds). The products involved take a large number of forms, from fresh fruit and vegetables to meat, poultry, fish and dairy products, to processed or packaged food available in retail outlets, to meals served in restaurants. They come from all countries of the world. The risk factors, and therefore the necessary checks, vary from product group to product group, and inspection and testing regimes take a wide number of forms.

Risks come not merely from the products themselves, but from the treatment they have received in growing to a marketable size and quality – for example, the use of pesticides is necessary in many instances, but pesticide residue levels have to be strictly monitored and controlled to avoid the introduction of new and potentially serious risk factors. Food additives also need to be controlled, as does product labelling and advertising.

Regulation is generally risk-based, but the complicating factor is that the risk can change quickly and outbreaks of food-related diseases can occur



unexpectedly, often in small, localized and remote geographical areas, and so effective monitoring, communication and rapid response systems have to be in place across the broad spectrum of products. Two recent examples that come to mind are the global responses to surprise outbreaks of BSE in cattle, and the unexpected detection of melamine in food products.

In a document of this nature, it is impossible to avoid making generalizations, the first of which is that regulatory systems for food need to be clear, consistent and fair to all parties, whilst simple enough to enable the rapid transport, sale and use of perishable products. The challenge is to simplify and deregulate routine controls wherever possible, without raising the overall risk unduly. This immediately raises the question of: what is an acceptable level of risk? In some societies the public expect the food they

buy to be risk-free, and yet this is not possible. The consumer, once made aware of some risk factors, has to bear some of the responsibility for purchasing healthy food, and for using it correctly, for rejecting unhealthy food. How can this system be organized nationally, regionally and internationally to keep the overall level of risk within acceptable limits?

The United Nations Food and Agriculture Organization (FAO<sup>2</sup>) recognizes that “*most countries have made significant efforts to strengthen their national food control systems in line with international guidelines developed by the FAO and the World Health Organization (WHO)*”. Yet it also accepts that “*progress toward establishing credible and effective food control systems worldwide, particularly among the least developed countries, has been too slow*”. The main

2) FAO, “Investing in Food Security”

reason for this is the reduction of discretionary funding allocated to food safety programmes by governments that have to juggle their priorities. It is an unavoidable fact that long-term programmes of investment are needed in many countries to build and sustain effective food control systems.

The Codex Alimentarius Commission (CAC) was created in 1963 by FAO and WHO to develop food standards, guidelines and codes of practice under the joint FAO/WHO Food Standards Programme. The CAC standards thus have the status of truly International Standards and may be adopted worldwide without any risk of breach of the provisions of the relevant World Trade Organization (WTO) agreements. The emphasis of

such standards is no longer merely on the quality and testing of the products, as productivity is becoming an issue owing to natural disasters and high population growth. FAO estimates that 30% of the food consumed in developing countries is perishable, and yet only 20% of that food has access to refrigeration. It is not surprising that, after harvesting, huge losses occur. Manufacturing guidelines and practices for improved productivity have, therefore, become part of the mix.

WHO estimates that each year foods contaminated with microbial pathogens cause millions of cases of acute diarrhoea, particularly among vulnerable populations, and that numerous other chronic diseases

worldwide, including cancers, may be linked to consumer exposure to foods with unsafe levels of chemical residues, environmental contaminants and other chemical hazards. While the regulation of food safety serves to limit diseases caused by unsafe food, it also has beneficial trade implications, and these are especially of importance to developing countries. The FAO reasons, though, that to achieve proper levels of production efficiency and consumer protection, public sector investment in food safety has to include some or all of the following:

- Updating or restructuring institutional set-ups, including legislative frameworks
- Strengthening food inspection services, recruiting and training necessary staff
- Upgrading laboratory analytical facilities
- Communication campaigns addressed to food handlers, stakeholders and consumers
- Commissioning relevant studies for use in developing appropriate food safety measures
- Participating in regional and international food safety intelligence networks, and
- Participating in international and regional food standard-setting bodies and other fora to ensure that these



standards take each country's conditions into account

**b) Regulatory systems:** The organization of food regulatory systems varies from country to country, but in the major developed countries there are a large number of similarities of approach. In the USA, there are two major food regulation agencies: the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). The majority of foods fall under the jurisdiction of the FDA's Center for Food Safety and Applied Nutrition (CFSAN), but meat, poultry and egg products fall under the USDA's Food Safety and Inspection Service (FSIS). Advertising of food is regulated by the Federal Trade Commission (FTC). It is acknowledged, and recent health scares have served to confirm, that the amount of food being consumed within the US from foreign sources is increasing, and a great deal of it comes from sources where the food safety systems are not well established.

Consequently, the FDA has seen the need to seek additional powers and to strengthen its response to the elevated threat from imported food, and has published a detailed Food Protection Plan. The new Food Safety Modernization Act (FSMA), signed into law in January 2011, allows for better protection of public health by strengthening the food safety

system. The act focuses on prevention rather than reaction to food safety problems. It gives the FDA new enforcement authorities to achieve higher rates of compliance and prevention. It holds imported food to the same standards. More information on the FSMA is available at [www.fda.gov/food](http://www.fda.gov/food)

In Canada, federal responsibility in this area is largely shared between Health Canada and the Canadian Food Inspection Agency (CFIA). The Food and Drugs Act delegates responsibility to Health Canada for establishing standards relating to the health, safety and nutritional quality of food. The CFIA controls food labelling, packaging and advertising in terms of the relevant act, and administers regulations under a number of other acts that cover meat, fish, and common agricultural products. CFIA's activities include:

- Protecting consumers from unfair practices
- Integrating the Hazard Analysis at Critical Control Points (HACCP) approach to food safety
- Sampling and testing for chemical (e.g. pesticide) residues
- Responding to food safety emergencies
- Verifying the quality and safety of food imports and exports

The CFIA has published a number of guideline documents for food importers. Import inspection programmes are risk-based and, as with those of other developed countries, based around relevant International Standards. Where products are found that do not conform to regulations, a sliding scale of sanctions is applied depending on the severity of the transgression. Detailed monitoring programmes exist for imported fruit, vegetables and honey, where risks from chemical residues are high.

A typical import inspection programme for meat or fish would include assessment of the inspection systems in place in the source country, inspection, testing and certification of the products against regulatory requirements, and statistically-based product sampling and analysis, together with inspection of relevant documentation, to assess whether requirements have been met. Inspection frequencies can be tightened or relaxed depending on compliance histories.

The CFIA's chemical residue sampling programme is a good example of a phased approach:

**Phase 1** (monitoring) involves the gathering of data from random statistical samples of fresh fruit and vegetables. Where maximum residue limits appear to have been exceeded, the product is put under the surveillance phase.



**Phase 2** (surveillance) is undertaken to conform provisional positive results and target problem areas. If any one of five samples is found to be out of specification, the product is placed under compliance status.

**Phase 3** (compliance) is intended to remove nonconforming product from the marketplace, and is targeted at the local source, such as the grower or shipper. Removals continue until all five out of five random samples are found to conform, whereupon the product is returned to the monitoring phase.

In the European Union, risk assessment is carried out separately from risk management. The European Food Safety Authority (EFSA) has been appointed within the EU as the body responsible for providing objective and science-based advice and communications in the field of food and feed safety as well as in related areas. The work of EFSA supports the risk management actions that are taken on a member state level. EFSA has appointed a number of scientific panels, responsible for risk assessment in the following domains:

- Animal health and welfare
- Food additives and nutrient sources added to food
- Biological hazards
- Food contact materials, enzymes, flavourings and processing aids

- Contaminants in the food chain
- Additives and products or substances used in animal feed
- Genetically modified organisms
- Dietetic products, nutrition and allergies
- Plant protection products and their residues
- Plant health

EFSA's advice, which is to a great extent derived from specific requests received, can lead to the adoption or amendment of relevant European legislation, facilitating approval decisions or the development of policy in new areas. The overall approach fits into a three-way risk analysis framework recommended by WHO and FAO, in which the elements of science-based risk assessment, policy-based risk management and broad-based

interactive risk communication are combined.

Risk management is then carried out on a member state basis, and uses relevant European and national legislation to achieve its objectives. Part of the reason for this is historical, as many member states had comprehensive and strict food safety legislation already in place before the creation of the EU. The EU's General Food Regulation 178/2002 lays down general principles and requirements of food law, and is supported by a number of specific regulations, including:

- Regulation 854/2004, covering products of animal origin intended for human consumption
- Regulation 853/2004, which lays down rules of hygiene for food businesses that use or process products of animal origin





- Regulation 852/2004, which deals with the hygiene of foodstuffs and lays down general hygiene requirements for all food businesses

National legislation then provides inspection authorities with the necessary powers. As an example, in the United Kingdom, the Food Standards Act 1999, the Food Safety Act 1990, and the General Food Regulations 2004 (as amended) create the necessary functions, powers, and offences. These acts are administered by the Food Standards Agency (FSA).

The aims of the food laws in the EU are to cover all stages of the food production chain, and to protect human life and health, together with consumers' interests, while at the same time harmonizing national requirements so as to permit the free movement of food and feeds within the single market. (This latter requirement is in fact central to much of the regulation within the EU.) Food must not be placed on the market if

it is unsafe, and International Standards provide much of the legislative detail. All food and feed produced in, or imported into, the EU or intended for export from the EU, is required to meet the relevant requirements of food law. In addition, the rights of consumers to safe food extend also to the right to receive accurate and honest information concerning food. A Europe-wide "rapid alert system" is in place.

Surveillance activities are aided by the recognition of the precautionary principle, whereby risk management may be conducted on the basis on the reasonable aim of the protection of health, even when full scientific data are not yet available to support decisions. This imposes significant responsibilities on food inspection agencies, which are, nevertheless, required to act in a proportionate and non-discriminatory manner.

Traceability of the origin of food and feed sources is a fundamental requirement of the EU's General Food Law, which also establishes

the principle that the responsibility for compliance with the law rests with the food business concerned. In many countries of the EU, a mechanism has been established whereby food businesses can notify the regulatory authorities of intended withdrawals of products from the market, and a number of communication channels exist to alert consumers and intermediaries of product recalls.

Generally within the EU, responsibility for enforcing the regulations is devolved to the local authority level, as well as to the border agencies. Thus, in the UK, local councils (municipal bodies) and port health authorities conduct inspections, using codes of practice provided by the FSA, which acts centrally to issue practice guidance to enforcement officers. The FSA has also produced guidance notes to the legislation for food businesses, in order to assist them in compliance. In deciding on the appropriate levels of response to established risks, a number of factors are taken into account, including the level of the public's appetite for risk; it is therefore implicit that consumers, once informed about risks, have a degree of responsibility to make their own informed decisions. The effectiveness of the work of the FSA, therefore, depends to a great extent on its ability to engage the public in the right way, and to an appropriate extent.

Coordination of activities at member state level within the EU requires planning. EU Regulation 882/2004 requires member states to establish a three- to five-year control plan. Such a plan would not only include compliance monitoring targets and emergency response mechanisms, but would also involve regular internal performance assessment of the national system, and provide a basis for external audit of competent national authorities at the European level.

**c) Standards, certification schemes, and where they fit into the food safety “landscape”:** Within the food and agricultural products sector a wide variety of standards exists. At international level, many product standards and test methods are developed by the Codex Alimentarius Commission (CAC), and by ISO/TC 34, *Food products*, and these often find their way into regulation owing to their international nature. Control systems for food safety also play a part, and these include implementation of Hazard Analysis at Critical Control Points (HACCP) principles, or the implementation of food safety management systems such as ISO 22000, *Food safety management systems – Requirements for any organization in the food chain*.

Surveillance of food products at market level and in production is not only carried out for

regulatory purposes, however, and the emergence of “private” or “consortium” standards in the marketplace now dictates that a great deal of product inspection takes place under the auspices of schemes such as those of Global G.A.P. or the British Retail Consortium (BRC). Typically, the use of these private standards is authorized by the granting of a licence to accredited conformity assessment providers, who then inspect and certify products against the standard. Certification opens the door for voluntary trade to take place. This has a number of implications for producers in developing countries. Positive ones first of all, as the producers who can demonstrate compliance can access large lucrative markets, but also potentially negative ones as some “traditional” suppliers in developing countries are now struggling technologically and financially to meet new standards with products that

were deemed acceptable in the recent past.

The food safety “landscape” is thus rather complicated, and consists of both regulatory and trade-related oversight both for safety and quality, and even for aesthetic reasons. Modern advances in mass communication have also placed food safety firmly in the public eye which has probably led to an increase in regulatory activities. Regulatory authorities are now becoming more proactive than ever before. The rapid communication of food safety “incidents” has, in turn, led to the development of new standards, schemes and response mechanisms in this sector.

One relatively recent development was the launch in 2000 of the Global Food Safety Initiative (GFSI). The GFSI, which is a retailer-driven group, aims to work on the continuous improvement



of food safety management systems. Its objectives are to :

- Maintain a benchmarking process for food safety management schemes to work towards convergence between food safety standards
- Improve cost efficiency throughout the food supply chain through common acceptance of GFSI-recognized standards by retailers around the world
- Provide an international stakeholder platform for networking, exchange of knowledge and the sharing of best food safety practices and information

GFSI has recognized a number of primary production and manufacturing schemes.

It is not surprising, given the number of standards and schemes available in this sector, that there is overlap between parallel initiatives, and this continues to pose a number of challenges that will need to be addressed.

## **Chemical and pharmaceutical products**

### **a) General considerations :**

Chemical-related diseases are responsible for the death or severe illness of millions of people worldwide. The regulation of chemical and pharmaceutical products covers a vast technical area, and at first sight market surveillance mechanisms might never be



expected to achieve the level of confidence in the safety of products on the market that can be achieved in most other areas. On the other hand, many hazardous chemicals are used in industrial settings by trained professionals, where greater levels of control can be achieved. Pharmaceuticals are manufactured by a limited number of companies that are subject to a number of defined pre-market controls. They are obtainable in their final form either by prescription of qualified medical personnel or over-the-counter from qualified pharmacists, or both.

Many controls exist, but nevertheless, the scale of the challenge is daunting. Many chemicals are found and used as part of separate chemical compounds or as components of mixtures. The number of individual chemicals is infinite, the list of possible effects is endless, and the number of usage scenarios is vast. Chemicals supplied to industry, trade or the end

consumer have to be manufactured, packed, labelled, traded, transported, stored at various stages of the product life cycle. They are often converted into another physical or chemical form or into a component or product, sold again and, finally, disposed of, all with acceptable levels of safety. Occurrences such as the Bhopal incident rightly grab the headlines and trigger major investigations, but every day, in millions of smaller-scale situations around the world, industrial and domestic chemical products and pharmaceuticals are involved in potentially life-threatening situations.

Fortunately, a great deal of progress has been made although the international systems for chemicals are not yet fully internationally harmonized :

- In the field of chemical nomenclature, the International Union of Pure and Applied Chemistry

(IUPAC) has laid down naming rules that are universally understood and in extremely wide use; this most basic of prerequisites to regulation is thus already in place

- The United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) has achieved very wide recognition by laying down criteria for classifying chemicals according to the health, environmental and physical hazards they pose, and in defining the hazard communication requirements for labelling and for inclusion in safety data sheets (SDS)  
Note: The GHS is not a formal treaty, but is rather a non-legally binding international agreement. Countries or trading blocs, therefore, are obliged in practice to enact legislation for its implementation
- ISO has published an International Standard on the sections, content and general format of the safety data sheet for chemical products (ISO 11014:2009, *Safety data sheet for chemical products – Content and order of sections*)
- In the EU, relatively new regulations for Classification, Labelling and Packaging (CLP) have been drawn up that are based on the GHS and that, in future, will be maintained at the UN, rather than at the EU level. The GHS provides a basis for globally uniform physical,

environmental, health and safety information on hazardous chemical substances and mixtures. The World Summit on Sustainable Development in Johannesburg in 2002 encouraged countries to adopt the harmonized system as soon as possible. The EU member states duly endorsed the UN's recommendation to implement the GHS in domestic law, and the result has been the CLP regulations

- The UNECE Sub-committee of Experts on the Transport of Dangerous Goods (UNSCETDG) meets regularly to make and revise recommendations for the safe transport of dangerous goods, including chemicals. These recommendations have found their way into legislation in a number of countries
- The EU's REACH Regulations (Registration, Authorization and Restriction of Chemicals) is probably the most complex piece of legislation ever produced by the EU. They entered into law in 2007 and will be phased in over a number of years. While REACH does not directly affect manufacturers based outside the EU, importers of their products based in the EU will inevitably request the necessary data from their manufacturers. This is bringing about a re-evaluation in the USA of the Toxic

Substances Control Act, which is administered by the Environmental Protection Agency, and is supported by numerous other regulations depending on the use of the products. China published proposals in 2009 for a set of regulations similar to REACH and which is referred to as the "China REACH" and came into effect in January 2010. It is similar to the EU REACH.

- REACH's method of working is discussed in more detail below.

**b) The REACH regulations:**

The EU REACH regulations were introduced in 2007 to impart, over time, greater knowledge of, and therefore facilitate protection against, the health, safety and environmental risks that emanate from chemicals that are used in the EU. Enforcement mechanisms and penalties are defined and are applicable across the EU. REACH aims to ensure that manufacturers and importers are responsible for defining the risks associated with all their chemical products manufactured in, or imported into, the EU in excess of 1 tonne. It was estimated in 2007 that there were no health and safety data for over 20% of the most frequently used chemicals in the EU, and that the data for another 65% were insufficient. REACH replaces about 40 separate pieces of EU legislation.

REACH affects manufacturers, importers and distributors of substances together with downstream users. Manufacturers and importers are required to register substances with the European Chemicals Agency (ECHA) and, in so doing, to submit prescribed data. The manufacture or supply of unregistered substances within the EU is, subject to certain conditions and time limits, prohibited. The type and quantity of data that are required to be submitted vary according to the quantity produced or imported, and highly hazardous chemicals are classified as “Substances of Very High Concern” (SVHCs). These substances, which typically include highly toxic, carcinogenic or environmentally harmful chemicals, may only be sold or used if they are “authorized”, and such authorization will depend on whether any safer alternatives exist, and the ease of control of the substance.

Inevitably, the consequences of EU REACH will be that a number of substances will be withdrawn

from the market, while the manufacture or import of articles that contain SVHCs in excess of certain limits will have to be notified to ECHA.

Note: This will have an immediate impact on other regulated areas, such as toys where, for the first time, toys that contain toxic substances above a certain concentration can be recalled under REACH regulations. Electronic components are similarly likely to be affected.

Other implications include :

- It is illegal to import unregistered substances
- Depending on the quantity of registered substances imported or manufactured, the technical dossier that accompanies the registration application has to include classification data, specified test data and guidance on their safe use. Above a lower limit of 10 tonnes per year, manufacturers or importers are required to also submit a Chemical Safety Report (CSR) that might include more detailed hazard data, an exposure scenario describing

how to use the chemical safely, and the results of a risk assessment

- After the dates stipulated, SVHCs will not be permitted to be used in the manufacture of, or to be present within, imported substances or goods
- Users and customers of manufacturing or importing firms will need to find out more about the composition of their products or substances and, where relevant, obtain from the supplier a safety data sheet

Surveillance of the EU REACH regulations in the EU member states is still at an early stage, but examples of actions undertaken include :

- Manufacturers, importers, wholesale or retail trading firms, and user entities, are visited and their documentation and physical arrangements for the control of chemicals, substances or articles that contain them, inspected
- Questionnaires are sent to firms in the supply chain asking for information that will enable inspectors to ascertain whether registration requirements have been followed correctly
- Requirements for the issuance or possession of safety data sheets are audited



- Infringements are logged, and appropriate corrective action or other follow-up is required
- Re-inspections take place

In June 2010, the Royal Society of Chemistry reported that one in four firms were not complying with chemical legislation in the EU, and thus the job of harmonization still has a long road ahead of it. Further details of the enforcement of REACH and CLP can be obtained from the ECHA website: [www.echa.europa.eu](http://www.echa.europa.eu)

### c) Specific measures affecting pharmaceuticals :

The regulatory challenge with pharmaceuticals is arguably greater than with any other product group. On the one hand, they are usually complex chemicals that could present a severe risk, but on the other, they are sold and used for medical purposes.

Therefore, many of the considerations of medical device regulation come into play. The risk posed by a pharmaceutical product is even quality-related, since any unwanted side effect reduces its acceptability vis-à-vis alternative products available from other manufacturers. Pre-approval testing of the product, clinical trials, licensing, development costs, patent expiry dates, and the likelihood of generic alternatives coming easily to the market, all play a part in decision making before the product is marketed. Throughout the lifetime of the product, its risks



are continually being evaluated, reported upon and compared with its therapeutic benefit.

Regulators such as the US Food and Drug Administration are often criticized for their slow approval system in the face of demonstrable medical need for certain products, but their approach has to be tempered by the need to show an acceptably low risk: benefit ratio, especially in light of the negative publicity and financial liability risk, not to mention the human suffering, caused by past scandals implicating the industry, such as thalidomide.

The major producers of pharmaceutical products have been in business for decades, admittedly under different names as there have always been a tremendous amount of consolidation, mergers and acquisitions in this industry, where even a single successful product development can massively impact bottom line performance for up to 15 years. Consequently, their systems of testing drugs,

and the scheduling and labelling regimes that accompany their marketing, have matured. Best practice has been harmonized to a great degree. Mass production techniques and the arrival of generics are relatively modern developments that have affected the marketing decisions of the manufacturers and, by implication therefore, the regulatory approach applied to this class of product.

The total cost of drug discovery and development tends to restrict the majority of new product (non-generic) manufacturing to these large companies. Indeed, only a small percentage of their products ever gain blanket regulatory approval and find their way into general worldwide circulation. Clinical trials, which in some jurisdictions can fall into three types or classes, are still only carried out on control groups of individuals and not on as wide a scale as the public might expect. Full-scale product testing in the “real” marketplace can be argued to

take place only after regulatory approval has been granted, hence the extremely risky nature of this business.

Regulatory approval by the FDA is subject to the product being shown to be *both* safe and effective. It involves the following steps:

- Filing an investigational new drug notice together with sufficient positive pre-clinical data to warrant proceeding to human clinical trials
- Up to three phases of ever-increasing levels of clinical trials, requiring the informed consent of participants:
  - **Phase I**, studying toxicity on a sample of healthy volunteers
  - **Phase II**, including dosage studies and studies of pharmacokinetic pathways, and
  - **Phase III**, large-scale testing in a representative population
- Post-market surveillance, involving close monitoring of the effects, especially the side effects, of the drug in use

In other developed countries, there is also often a further requirement to show cost-effectiveness, especially in markets where state health authorities, such as the National Health Service in the UK, have a major



interest in obtaining value for money.

In other areas of the world, pre-market approval follows similar, if not identical, patterns. Post-market surveillance, or the monitoring of a drug in use to observe deviations from clinical trial results in the general population, has to be carried out by a complaints mechanism whereby the medical profession reports adverse or unexpected effects. In the USA, post-market surveillance is carried out by the FDA under its “Medwatch” system, whereby medical professionals as well as the public can report drug effects. In all cases, the regulatory agency has the right to withdraw or restrict in some way its prior approval of a drug that has proved to have unexpected side effects or has shown itself to be ineffective in certain scenarios. In Europe and some other parts of the world, this monitoring phase is often referred to as “pharmacovigilance”.

The following regulatory agencies have extensive websites and can provide further information:

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- Japanese Ministry of Health, Labour and Welfare
- Indian Central Drugs Standards Control Organization (CDSCO)

A number of pharmaceutical industry associations exist that can provide detailed information from the manufacturers’ side and, in the UK, there exists the National Institute for Health and Clinical Excellence (NICE), which has published a number of good practice clinical guidelines.

Some criticisms of regulatory processes for pharmaceuticals warrant mention:

- It has been stated that the regulatory approaches to pharmaceuticals differ between the major economies in that the US approach taken by the FDA is characterized as one of “managerial discretion and adjudication”, whereas the approach taken in Canada involves consultation, and in Europe a certain amount of bargaining takes place. The implication is that



different decisions can be taken in different jurisdictions

- In the single market of the EU, there has to be mutual recognition of different member states' product licensing decisions, but differences in evaluation processes remain
- One consequence of the on-going harmonization of regulatory criteria could be that marketing approval decisions will be made at a level perhaps that inadvertently, shifts the emphasis onto more and more stringent post-market surveillance techniques
- From the consumer's point of view, the wrong message is sent when a drug is available on prescription in only one country, but over the counter in another

It, therefore, seems clear that the safety and effectiveness of pharmaceutical products cannot be demonstrated beyond all reasonable doubt merely by a combination of clinical trials and other pre-market approval techniques. Going forward, it will be in the best interests of the drug companies to enhance their own post-market follow-up techniques to protect their market share as well as the health of the general public.

**d) The developing country perspective:** Some developing countries face a dilemma in the regulation of chemicals and pharmaceuticals, in much the same

way as for medical devices. They are not in general "close" to manufacturers. They do not possess the sort of in-depth expertise that is required for decision making, and the likely response to calls for the voluntary reporting of adverse effects by knowledgeable consumers is almost guaranteed to be poor. On the other hand, they cannot afford to throw open their markets to the unlimited and uncontrolled entry of potentially unsafe products from all countries just to keep costs down. There is a trade-off between the strategy of following the decisions of another trusted country or region (such as the USA or the EU) and the implicit costs of doing so.

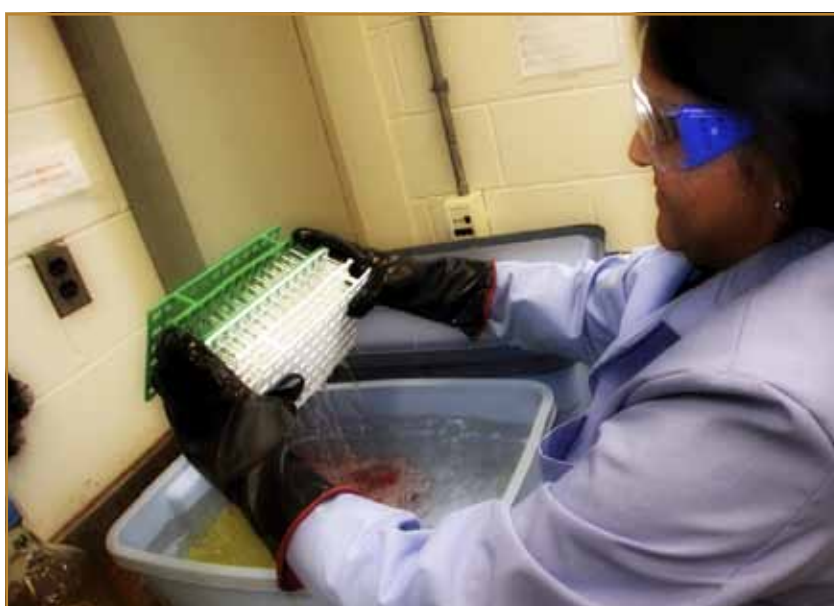
Existing internationally harmonized arrangements go only part of the way to guaranteeing compliance or to ensuring an affordable, yet acceptable-risk, outcome. The opportunity cost of neglecting generic drugs when

large populations need them, has to be weighed against the perceived product safety assured by taking the higher-cost alternative. The answer must be found not in the development of all countries to super-regulator status, but in the judicious management of risk, in the exploitation of synergies offered by partnering with other countries in larger regional economic groupings or free trade areas, and in the negotiation of special dispensations in international fora.

## Personal Protective Equipment

### a) General considerations:

The term Personal Protective Equipment (PPE) covers a wide range of devices and appliances designed to be worn or held for protection against one or more safety and health hazards. Thus, items such as protective headgear, gloves, safety shoes as well as respirators, self-contained





breathing apparatus and eye protection devices fall under this heading. As a consequence, a large number of international, regional and national product standards exist that cover the technical requirements for these products, and in regulations based on them, it is generally the practice to use a classification system for PPE, based on risk.

Most such items are used in an employment situation, although protective equipment used in sport and leisure also fall under the same heading. A variety of regulatory/market surveillance authorities are delegated the task of controlling these products; in a number of developing countries, those items of PPE that are

used in the workplace tend to be covered by regulations administered by the relevant manpower or labour ministry.

By definition, items that are used or worn in hazardous situations require special monitoring; should such an item fail, the user or wearer is by default automatically placed in a dangerous, even life-threatening, situation. It is, therefore, not surprising that market surveillance systems for these products rely just as much on monitoring in use or at the workplace as on approval of the new finished article. Documentation, expiry dates, and standard operating procedures are extremely important in this context.

One advantage of the usage situation for most of these products is that user complaints from the workforce, which tends to be unionized, are readily forthcoming. Employers have a duty to ensure that their workers are suitably protected, and face stiff penalties, even criminal liability, if they fail in this regard. In many countries, the public outcry that attends the failure of employers to live up to their responsibilities to protect their workers is sufficient to ensure a high degree of compliance. On the other hand, it is a known fact that some large tenders in the construction and raw materials extraction/beneficiation industries have been won and awarded to companies on the basis of low cost, only to find that those low cost estimates are based on failure to provide the correct protective equipment for workers.

In some jurisdictions, the regulatory situation is complex. For example, in the United Kingdom, hearing protectors and some respirators used in the workplace fall under different regulation regimes to those for protective clothing, safety footwear, etc., while motorcycle helmets worn by employees in the course of their duties fall under road traffic legislation. It is not uncommon, therefore, for a number of different regulations to be competing in this area.

In general, PPE regulations require that appropriate

protective equipment be supplied in the workplace whenever the situation demands it, and that the individual items of protective equipment be subject to a pre-assessment as to their suitability, followed by checks on their maintenance, storage, accompanying instruction leaflets, standard operating procedures or training provided to employees.

In assessing suitability prior to use, employers should:

- Determine whether the proposed equipment is appropriate for the hazards likely to be encountered – examples of this could include the decision between respirators and self-contained breathing apparatus, or between safety spectacles,

eye goggles and full-face splash-masks

- Satisfy themselves that the use of the proposed equipment will actually reduce the total risk – in other words, when in use does it add any unforeseen risks that might make the situation worse?
- Assess whether the equipment can be adjusted to fit the wearer properly
- Take into account the physical demands on workers from using the equipment – for example, the wearing of heavy, hot protective suits might require that the time workers are required to be at the workplace be limited, and that extra rest breaks be provided

- Consider possible allergic reactions to the equipment – for example the severe skin conditions sometimes caused by the wearing of surgeons' latex gloves that contain too much extractable protein residue from the production process
- Assess the compatibility of different types of equipment intended to be worn simultaneously

#### b) The European Union Personal Protective Equipment Directive:

The Council Directive 89/686/EEC, as amended in 1993 and 1996, lays down a comprehensive set of rules that must be followed in the EU for placing on the market, free movement within the EU, and safety and quality aspects of PPE. It is a detailed document that, when taken together with the large number of European and International Standards that lay down “deemed to satisfy” provisions, constitutes an extremely comprehensive solution to the problem of controlling the marketing and use of such equipment.

It recognizes that national provisions within EU member states make the use of PPE in the workplace compulsory when shown to be necessary, and lay down harmonized basic requirements, conformity with which may be presumed based on an attestation of compliance with the



relevant standards. EU member states may not prohibit, restrict or hinder placing PPE or their components on the market if they conform to the provisions of the PPE directive and bear the CE-marking.

The steps in the regulatory process are essentially as follows :

### 1. Technical documentation before market entry:

Before placing the PPE product on the market, the manufacturer or, in the case of a foreign manufacturer, its authorized representative, is required to assemble documentation that comprises all relevant data on the means used by the manufacturer to ensure that the PPE in question complied with the relevant basic requirements. For items that require a type evaluation [see 2 below], this documentation must include the manufacturer's detailed technical file

### 2. Submission of a model for type-examination:

Before series-production may take place for all except PPE models of "simple design", a model must be submitted, together with the technical file, for type-examination by an approved inspection body

3. Certain products of simple design are exempted from type-examination. These are detailed in the directive

4. Production of PPE is subject to the manufacturer undergoing

and passing, according to its choice, one of two defined checking procedures, followed by its making a formal declaration of conformity :

**Option A** is the quality control system for the final product, and includes :

- Proof that the manufacturer has taken all steps necessary to ensure that the manufacturing process, including the final inspection of the PPE and any tests, ensures the homogeneity of production and the conformity of the PPE with the type described in the type-approval certificate and with the relevant basic requirements of the directive

- A notified body of the manufacturer's choice carries out necessary random checks, examinations and tests as defined in the applicable harmonized standards, to assess the conformity of the product

- A test report is issued which, if it concludes that production is homogeneous and the product conforms to the relevant basic requirements, must be presented on request by the manufacturer ; if the report is not positive, suitable corrective action must be taken until it is

**Option B** is the ensuring of quality of production by means of monitoring, and includes :

- Submission by the manufacturer of a detailed application



for approval of its quality control system to a notified body of its choice

- The examination, under the quality control system, of each PPE and the carrying out of appropriate tests to check their conformity to the basic requirements of the directive
- A detailed assessment by the notified body of the adequacy of the quality control system, followed by the issuing of a reasoned assessment decision
- On-going supervision by the notified body of the quality control system, once approved, by means of periodic audits and unannounced visits to carry out inspections of the product, testing and storage sites and all documentation including documentation on the quality control system, technical documentation of the product and the quality control manuals
- The issuance of an audit report which, if it concludes that production is homogeneous and the product conforms to the relevant basic requirements, must be presented on request by the manufacturer; if the report is not positive, suitable corrective action must be taken until it is.



**e) Consequences of CE-marking:** Following the above procedure, the declaration of conformity affixed to the product by the manufacturer is in the form of the CE-marking. Within the EU, in general, if a member state establishes that the CE-marking has been affixed unduly, then the manufacturer of the product or its authorized representative is obliged to make the product conform and to end the infringement under conditions imposed by the member state in question.

Where nonconformity continues, the member state is required to take all appropriate measures to restrict or prohibit placing the product on the market, or to ensure that it is withdrawn from the market.

## Toys

### a) General considerations:

The need to ensure the safety of toys entering the market poses a special challenge for legislators and standardizers as well as for market surveillance authorities. The concept that the informed consumer has to bear some of the responsibility for his or her own purchase and use of products, has diminished. Parents still have responsibility for purchasing safe toys for their children. Provided they, and the supply chain, have access to the necessary information, that complaints are notified, and that product recalls actually take place in the expected way, then the risk at the

point of purchase should be the same as for any other product.

The difference comes about when the products are put into use. Children are an extremely vulnerable group, as they cannot always be guaranteed to use a product in the way its manufacturer intended. Extremely young children are at greatest risk, as they do not yet possess any mechanism for aligning the issues of safety and desirability of the product. It often occurs that the toy a child likes best is laden with more risks than others. It is, therefore, not surprising that toys are the most frequently notified product category in the EU's RAPEX system.

**Table 2**, which is not claimed to be comprehensive, gives an idea of the type of risk a child can encounter playing with toys.

The standards listed in **Table 3** below give an example of how the standards community has responded to these challenges.

**b) Regulatory approaches:** The standards listed in **Table 3** and their “deemed to satisfy” status in regard to the provisions of legislation such as European directives, are a good indication of international commitment to a unified approach to toy safety regulation. More, however, needs to be done. Different countries still adopt differing approaches, develop different national standards in some areas, and vary in their views as to the level of

intervention required. Batch testing on product samples alone is insufficient to guarantee that unsafe products will not enter the market. Quality management systems are needed to ensure that the product designed is the product actually produced. Products that meet the requirements of standards can still become the subject of notifications when previously unforeseen risks present themselves in use. Therefore, robust notification and product recall systems have to be in place.

In the European Union, the Toy Safety Directive 88/378/EEC laid down essential safety

requirements (in essence, that toys have to be safe) for market entry into the EU. Conformity to the appropriate standards, in particular the relevant parts of EN 71 listed above, led to a presumption of conformity to the directive which, in turn, led to implied permission for the products to bear the CE-mark. Recently, although the 1988 directive has worked well, changes in technology and the emergence of new risks have necessitated the adoption of a new directive, 2009/48/EC, which substantially amends the old directive, and came into force in July 2009. Implementation in national legislation is expected



**Table 2 – Toy category versus risk**

Toy category	Risk
Activity toys (swings, slides, trampolines, bicycles, scooters, skateboards, strollers or buggies, etc.)	Physical harm due to falling, getting stuck in mechanisms, collisions
Chemistry sets or products containing chemicals	Ingestion, inhalation, poisoning, allergies, burns
Scented or flavoured toys, teethingers	Suction, ingestion, poisoning or allergy due to biting, suction, leakage
Painted wooden toy products	Poisoning through ingestion of lead etc., injury from wood splinters
Expanding toys	Suffocation, choking when toy expands in mouth
Battery-operated or electrical toys	Electric shock, poisoning or explosion due to swallowing or inappropriate disposal of batteries
Toys with small removable parts	Choking or injury caused by putting parts into mouth, nose, ears, etc.
Mechanical toys	Injury due to contact with sharp edges, moving parts
Toy chests, play houses, enclosures	Suffocation due to lack of ventilation
Paints, drawing sets	Poisoning, inhalation, swallowing, allergic reaction, skin absorption of toxic elements
Toys that fire projectiles	Injury to face, eyes, suffocation from blocked airways

**Table 3 – Examples of Standards used in regulations**

<b>ISO 8124-1:2000</b>	Safety of toys – Part 1: Safety aspects relating to mechanical and physical properties
<b>ISO 8124-2: 1994</b>	Safety of toys – Part 2: Flammability
	Ingestion, inhalation, poisoning, allergies, burns
<b>ISO 8124-3: 1997</b>	Safety of toys – Part 3: Migration of certain elements
<b>ISO 8098: 1989</b>	Cycles – Safety requirements for bicycles for young children
	Suffocation, choking when toy expands in mouth
<b>EN 71-1</b>	Safety of toys – Part 1: Mechanical and physical properties
<b>EN 71-2</b>	Safety of toys – Part 2: Flammability
<b>EN 71-3</b>	Safety of toys – Part 3: Specification for migration of certain elements
<b>EN 71-4</b>	Safety of toys – Part 4: Experimental sets for chemistry and related activities
<b>EN 71-5</b>	Safety of toys – Part 5: Chemical toys (sets) other than experimental sets
<b>EN 71-7</b>	Safety of toys – Part 7: Finger paints – Requirements and test methods
<b>EN 71-8</b>	Safety of toys – Part 8: Activity toys for domestic use
<b>EN 71-9</b>	Safety of toys – Part 9: Organic chemical compounds – Requirements
<b>EN 71-10</b>	Safety of toys – Part 10: Organic chemical compounds – Sample preparation and extraction
<b>EN 71-11</b>	Safety of toys – Part 11: Organic chemical compounds – Methods of analysis

by January 2011, although there will be a longer-term phase-in of certain requirements, especially chemical requirements, and thus some parts of the old directive will remain in force for some time. Important new changes to the directive include limitations or complete bans on the inclusion of some harmful chemicals in toys, and either a full ban on allergenic substances or stricter labelling requirements where these are shown to be potentially allergenic only to some consumers. Enforcement will clearly involve much greater reliance on complex and extremely sensitive testing in the future and, of course, the new requirements are inextricably linked to the EU's REACH regulations. Some aspects of toy safety, where these are not covered directly under the Toy Safety Directive, nevertheless fall under the General Product Safety Directive (GPSD).

Market surveillance authorities in the EU member states have the power to demand immediate withdrawal of a toy product from sale if it presents a safety hazard,

via the RAPEX recall system. One forward-looking aspect of the Toy Safety Directive is the requirement that where a standard is not specified within the directive, the closest applicable national or International Standard is to be applied; this is intended to ensure that new and innovative toys are also confirmed to be safe before entering the market. A number of third-party consultancies have introduced supply chain risk management solutions to assist toy suppliers to navigate through the complex set of obligations that they now have to meet.

PROSAFE, the Product Safety Enforcement Forum of Europe, has recently undertaken research in terms of a joint market surveillance action on toys, involving a number of market surveillance authorities from the European Economic Area [European Union countries and European Free Trade Association countries (Norway, Iceland, Lichtenstein and Switzerland)]. Within this group of countries, market surveillance authorities responsible for toy safety have formed

an administrative cooperation group, known as TOY-ADCO, which exchanges information between members. The joint market surveillance action provided a large amount of specific information about the hazards investigated in specific toy product groups, but also enabled its participants to gain first-hand experience of working together on a large-scale market surveillance initiative.

In the United States, market surveillance is undertaken by the Office of Compliance of the U.S. Consumer Product Safety Commission (CPSC) under the Consumer Product Safety Act. The CPSC has issued a number of mandatory safety standards, and operates a recall system. The "Fast Track Recall System", whereby manufacturers or members of the supply chain can voluntarily notify the CPSC of product safety issues, accounts for the majority of recall notifications, and works in such a way that if the manufacturer voluntarily recalls defective and unsafe products within 20 days of making a notification, the CPSC does not need to undertake a preliminary hazard determination and can immediately assist the firm with its product recall programme, thereby saving time and resources.

A number of related ASTM standards exist and ASTM standards are noted as national standards when they have international





acceptance. With toys, the CPSC sometimes requires that manufacturers display an age warning symbol to indicate the intended age of users of the product. One notable recent development in the U.S. has been the passing into legislation of the Consumer Product Safety Improvement Act in 2008, which goes further than previous legislation, especially in the case of toys where, for example, it places strict limits on the content of lead and phthalates in toys for young children, both of which can cause severe health hazards by ingestion.

China is the largest manufacturer of toys in the world, and therefore has a special responsibility to control the safety of these products at source. In 2007, the Chinese compulsory certification requirements were expanded to include toy products, and toy manufacturers are obliged to apply to one of three certification agencies for inspection and certification, without which the toys may not be sold internally or exported. The same requirement applies to imported toys. The EU has been active in working with Chinese toy manufacturers to exchange RAPEX information and assist the Chinese authorities in tracing, feedback and follow-up mechanisms for notified products. A specific “Roadmap for safer toys” was signed between the EU and China in 2006.

**c) Implications for developing countries:** The complex



mix of regulatory requirements in large markets for toy products requires that manufacturers, whether in developing countries or not, face the same set of challenges to establish a comprehensive risk management system that will enable them to market their products without contravening numerous regulations. Those who would choose to ignore such regulations leave themselves open to costly recall procedures, accompanied in some cases by product liability claims and potential insolvency or even criminal prosecution. Regulators in developing countries would be well advised to base their product safety requirements around widely available standards that have been accepted as sufficient to satisfy strict regulatory needs in mature regulated markets elsewhere. Products that bear appropriate attestations of conformity, such as

the CE-marking are, in theory, likely to be compliant. However, market surveillance authorities need to be vigilant and keep abreast of product safety recalls in other jurisdictions, to be on the lookout for fraudulent supplier declarations, and to bear in mind the implications of EC Regulation 765.

Importers of toys and consumers in developing countries face the same set of decisions as with other types of regulated products. Good advice would include:

- Looking for the CE-mark on a toy – and if it does not bear the CE-mark, trying to ascertain why it is absent
- Rejecting products that do not carry labels, warning signs or include instructions in the local language
- Looking for and paying due attention to age warnings on toys.

# CONCLUSIONS



Regulatory needs and the responses to them might differ in detail between countries and regions, but there is already much common ground, especially in the sectors highlighted in this document.

Resource limitations apply everywhere, not just in developing countries, and a risk-based approach to market surveillance, both at the pre-market and post-market levels, coupled with rapid communication to the consumer level is generally agreed to provide the most appropriate level, of monitoring and response. The ultimate goal of “one standard, one test (or one certificate of conformity), accepted everywhere” remains a challenge, but promises a solution to the needs of developing countries. Indeed, scarce resources would often be better allocated to improved promotion of consumer awareness and upgrading basic inspection, testing and monitoring

capabilities than on acquiring costly esoteric test and measurement facilities that are likely to remain unused most of the time. Regional synergies between developing countries need to be better exploited than at present.

Global trade has increased in pace with the more widespread use of first party (suppliers’) declarations of conformity, but this does not mean that risks have disappeared, and the management of those risks still remains a necessity. Where developing countries can, and often should, benefit from placing greater reliance on products that have been shown to be acceptable for entry into other more developed and regulated markets, they need to remain vigilant in the face of increasing volumes of counterfeit goods, or products bearing false declarations of conformity, targeted at those markets where surveillance is at its weakest. While regulatory needs remain

much the same at the most basic levels, the response-landscape for meeting those needs is, nevertheless, changing and does vary between countries and regions.

The requirement for International Standards to be globally relevant, together with greater cooperation between standardizers and regulators, promises better technical tools to meet the needs of regulators. The on-going expansion of the range of available standards into the service sector and the work of CASCO will lead to more precise guidance to satisfy the operational needs of market surveillance authorities, or to cover the competence of their personnel. More standardized approaches to the way the scale of market surveillance activities may be needed to be ramped up or down in the face of changing risk patterns. There have been calls for standards that lay down good practice principles

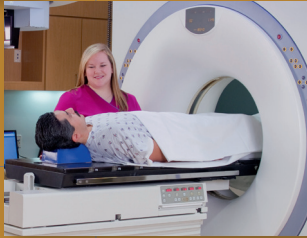
for the application of restrictive measures, sanctions and product recall, as well as the level and format of information that should be exchanged between market surveillance authorities. In addition, there is perhaps further scope for the development of good practice guidance standards on how best to meet conformity assessment or market surveillance requirements.

Challenges and responsibilities will still remain, however, that cannot simply be solved by standards alone. Not all regulatory aspects relating to a given product can be included in a single standard. A standard can list the technical requirements for a product, that are assessable in the final product, but that

might not be sufficient to meet the needs of a regulator who wishes to inspect production controls during manufacture. A second standard, or other set of standard operating procedures, might be needed. Standards can be used to lay down good practice provisions for what is needed in an effective market surveillance programme, but they may not lay down the rules for their own application. Responsibility for that must always be the standards user's. Consumers, once made aware of product risks, also need to take some of the responsibility for their management.

In this context, national standards bodies have a duty to promote quality and consumer awareness in their territories, and regulators

have an interest in obtaining better and more consistent outputs from conformity assessment bodies and even from accreditation bodies. Consumer bodies have a part to play in making sure that information relating to unsafe products is disseminated, and that complaints are lodged with the correct authorities. This is especially true in developing countries which require better levels of support. Where consumers can play a part in the standards-setting process, at the same negotiating table as the regulators, the result will always be a better standard, and this will facilitate regulatory compliance.



**ISO Central Secretariat  
1, ch. de la Voie-Creuse  
Case postale 56  
CH-1211 Genève 20  
Switzerland**

**Tel. +41 22 749 01 11  
Fax +41 22 733 34 30  
E-mail [central@iso.org](mailto:central@iso.org)  
Web [www.iso.org](http://www.iso.org)**

**ISBN 978-92-67-10594-9  
© ISO – October 2012**