POSSIBLE CONTRIBUTIONS OF ISO/CASCO TO THE ISSUE OF MARKET SURVEILLANCE

WORKING DRAFT

1 Introduction

Market surveillance (MS) covers a number of regulatory and voluntary mechanisms which ensure that products and services proposed to consumers and users comply with regulatory or voluntary requirements. It can be conducted by public authorities responsible for consumer protection, frauds and/or competition laws. It can also be conducted by certification and accreditation bodies to control compliance with their requirements at the level of the relevant markets or by consumer organizations sampling products and services to identify or substantiate possible recurrent problems.

Market surveillance is an indispensable complement to legislation relating to safety or other societal interests (e.g. environment) and to the facilitation of trade resulting from simplification of upstream pre-market controls. Liberalization and globalization of trade has given an international dimension to market surveillance in its various forms, resulting in a freer circulation of goods including across frontiers through the elimination of technical barriers to trade. Recent evidence of malpractices resulting in threats to safety or threats to the environment has given high exposure to the need for market surveillance. Public authorities responsible for market surveillance increase their networking and exchange of information. Manufacturers, transporters and retailers increase collaboration to secure that the global supply chains clarify responsibilities and do not result in higher liabilities.

ISO itself is directly concerned, through the possible negative impact on ISO's reputation of a growing lack of confidence in certification and accreditation and the conformity assessment oversight processes based on ISO Standards.

There is therefore a growing interest in the role that Market Surveillance (MS) has in addressing these concerns.

This discussion paper is meant for the membership of CASCO in order to identify ISO’s possible contributions on this issue. It aims to:

a) identify the areas of MS which could be addressed by ISO at the international level;
b) determine if there is sufficient consensus on the potential need for international level of work on MS and if so what it should include as its scope;
c) determine if there is a need for generic standardized base document for MS processes or other ISO deliverables; and
d) determine how ISO can contribute to MS activities in the future.

Additionally it is meant as a background document for the CASCO CPC and STAR who will develop it further for the CASCO MS workshop in October 2008.

2 Background to MS within ISO

Both COPOLCO (16/2004) and DEVCO (20/2007) have recently passed resolutions on MS in response to initial enquiries by CASCO. The COPOLCO resolution focused on the need for guidance on MS to ensure consumer safety, whereas the DEVCO resolution expressed willingness of developing economies to support CASCO on MS issues, with the concern of the possible increase in low quality/safety products being dumped on world markets.

UNECE have also recently taken a resolution (2007) on the need to work jointly with CASCO on MS issues in relation to regulatory and counterfeiting aspects.

OECD has, for some years addressed the issue.

Both in the USA and in the European Union, increased attention is being paid to the issue of MS by public authorities and the private sector.

Within CASCO, MS was discussed in early 2004 with the intention of developing an international guidance document on MS. The CPC was unable to reach consensus on this.

Only in 2007 did MS again come to prominence, because of growing concerns on the global scene, as indicated above.

3 Identification of MS activities

The scope of activities covered by MS can vary significantly from sampling to pre-market type approval to "retail outlet" sampling to product recall to disposal of the product. Basically 5 types of conformity assessment activities (sampling, testing, certification, inspection and SDoC) are involved in MS.

MS surveillance can be considered in 3 broad contexts, although there is some overlap in the processes used in each:

i. Regulatory

In the regulatory context it is focused on ensuring the correct application of legislation. Regulatory MS is usually associated with health, safety and fair trading (and now more often with the environment). It is performed by public authorities, but may rely on the use of (accredited) testing, inspection and/or certification, with possible requests of compliance to the relevant conformity assessment ISO/IEC standards. MS in the regulated areas ensures that products and services comply with regulatory requirements and usually implies legal consequences and action for non-compliance. Regulatory requirements may themselves refer to consensus based standards (cf. WTO/TBT, EU “New Approach” or the publication on the “Use of ISO and IEC standards in the context of technical regulations).

ii. Voluntary

In the voluntary context, MS can apply as a necessary part of the normal conformity assessment framework regardless of whether it is 1st, 2nd or 3rd party. This would include MS related to product certification schemes or the certification to Management Systems Standards.

MS is also associated with Suppliers Declaration of Conformity (SDoC); the level of confidence in SDoC is related to the level of market surveillance.

Functional conformity assessment can range from market surveillance on the compliance of the Accreditation Body (AB) with the MLA criteria by a 3rd party to the verification by the AB of the certification done by the CB on the organization that has been certified.

iii. Voluntary in the context of counterfeiting

In this context MS is used to identify counterfeit products and to alert the appropriate authorities. Counterfeiting may or may not be associated with noncompliance with technical regulations. Counterfeiting accounts for 7 to 10 % of world trade. Where counterfeit goods have an impact on health and safety and where the consumer is placed at risk adds another dimension to this type of MS. The MS activity is complicated due to the role and responsibilities of the Authorities and that of Business. The skills and processes involved in determining if a product is counterfeit can be significantly different and can be unique to the particular brand or object being reviewed. It has been suggested that the regulatory infrastructure can be used in parallel to identify counterfeit goods.

4 Market Surveillance in different markets

There are 2 broad categories of markets. The Business to Business (B2B) and the Business to Consumer (B2C). The level of knowledge and expectations in each is different. There is a greater need for MS in the B2C market as the consumer has the expectation that products should continuously meet standards. The required level of knowledge of the B2C market is less than that of B2B.

5 Traceability

Traceability of products and information in MS is important when there is an identified problem and where there is a need for follow up actions. Today it is possible to identify a single item back to its production source or batch. Criteria need to be implemented to enable the transfer of information between all interested parties in MS related issues. ISO can contribute to the traceability of products and information in this respect. ISO has already developed a standard on traceability in the feed and food chain (ISO 22005).

6 Who are the Interested Parties in MS?

Depending on the focus of MS in question, the parties involved in MS activities are:

i) In the regulatory context:

Governments and Trade officials
Regulators and Authorities
Manufacturers/Producers
Retailers
Insurance companies
Standards Bodies (International, regional and national)
Users and Consumers
Certification bodies and Inspection Bodies
Testing laboratories
Accreditation bodies

ii) In the voluntary context as part of the normal functional conformity assessment activity:

Manufacturers/Producers
Service providers
Retailers
Insurance companies
Standards bodies (International, regional and national)
Users and Consumers
Certification bodies/Inspection bodies
Testing laboratories
Accreditation bodies
Media

iii) In the context of counterfeiting

This would include all of the above (i and ii). The involvement of the authorities and regulators would depend on the extent that counterfeiting impacts on consumer health and safety.

7 Possible ISO/CASCO contributions to MS

There are 4 possible contributions to MS that ISO/CASCO may consider:

i) The regulated context

To take on a role within the regulatory arena without the support and participation of the authorities will not be accepted. Indications are that support from regulators in developed regions may be more difficult to obtain. However in developing regions the situation may be different. ISO does have a legitimacy to include future work on the regulatory aspects of MS provided that there is sufficient "buy in" from regulators and government authorities.

Possible activity for ISO/CASCO:

To develop a guidance document for market surveillance authorities which would describe the possible use of the CASCO toolbox in the context of MS by any of the interested parties, when convenient.

ii) In the conformity assessment context

ISO has a natural mandate to ensure that the MS activities associated with the normal conformity assessment processes and activities are done in manner that is consistent and harmonized throughout the world. This would include MS of the conformity assessment oversight processes.

Possible activity for ISO/CASCO:

To develop a guidance document taking into consideration the CASCO toolbox for some or all of the conformity assessment activities (accreditation, certification, inspection and SDoC) used to demonstrate compliance. This would also include MS activities associated with product certification.

iii) In the counterfeiting context

ISO has a weaker impetus at this stage for pursuing MS associated with counterfeiting unless supported by authorities and business. However due to the potential economic, health and safety issues associated with counterfeiting this could be a future work item for ISO and should be explored further by ISO/CASCO.

Possible activity for ISO/CASCO:

To develop a guidance document taking into consideration the CASCO toolbox for those aspects related to counterfeit goods and their detection.

iv) Common deliverable

There is benefit in exploring the development of a core set of requirements which are common for all types of MS. This would be considered a "master" document which would ensure consistency and harmonization of basic MS activities irrespective of the MS context. The authorities and sectors could add to the core set of requirements where necessary. There is a need to have a common understanding of MS definitions and terminology at the international level.

Possible activity for ISO/CASCO:

i) To develop a guidance document containing a set of core elements which would address MS at the generic level for all contexts.

ii) To develop a guidance document on definitions and terminology used in MS to ensure consistency of interpretations and application.

8 Product recall

Product recall is a possible follow-up of any MS activity be it in the regulatory or voluntary areas. Product recall closes the loop ensuring that noncompliant products have been removed from the market or prevented from entering the market. ISO has set up a project committee to prepare a standard on product recall. The initiative was proposed by ISO/COPOLCO , the ISO Committee on Consumer Policy.

9 Conclusions

ISO needs to identify where it can legitimately addresses the issues of MS at the global level. The paper identifies 4 possible MS contexts for ISO/CASCO to consider in relation to how CASCO will contribute to future MS activities. ISO/CASCO should review these possible contributions and make recommendations and prioritize for further actions. It should also guide CASCO in developing the content and focus of the MS workshop scheduled for October 2008.