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MARKET SURVEILLANCE

UPDATES FROM REGIONAL GROUPINGS AND THE ADVISORY GROUP ON MARKET SURVEILLANCE ("MARS" GROUP)

Market surveillance: general concept and how it relates to the activities of the Working Party

Note by the secretariat ^(*)

Summary

At its eighteenth session, the Working Party on Regulatory Cooperation and Standardization Policies adopted the terms of reference of the market surveillance model initiative as described in ECE/TRADE/C/WP.6/2008/13 and requested the secretariat to report on the General Market Surveillance Procedure (ECE/TRADE/C/WP.6/2009/11, para. 74).

This document introduces the General Market Surveillance Procedure. It explains in simple terms what market surveillance is, how it relates to the activities of the Working Party, and what the main phases of the Procedure are. The document is submitted to the Working Party for consideration.

^(*) The present document has been submitted after the official documentation deadline by the Trade and Timber Division due to resource constraints.

1. The objective of this document is to provide an introduction to the General Market Surveillance Procedure (GMSP). It explains in simple terms what market surveillance is, how it relates to the activities of the Working Party, and the main phases of the GMSP.

2. In recent months, dangerous and counterfeit goods, e.g. hazardous children's toys, contaminated milk, falsified spare parts for cars, have caused public outcry on national markets all over the world. Proliferation of these products poses a serious threat to human health and to the natural environment. It also undermines local industry, which is frequently unable to compete against a massive inflow of cheap and inferior-quality goods. Market surveillance is the main regulatory response to ensure that products placed on the market, whether imported or produced locally, conform to national technical regulations and are not counterfeit or pirated.

3. There are two fundamental reasons for which countries need to develop an efficient market surveillance system:

(a) To remove illegal and unsafe products from the market. As no conformity assessment¹ conducted before products are placed on the market can prevent all faulty products from slipping through the net, public authorities must monitor products once they are made available to buyers.

(b) To ensure that market conditions are fair: suppliers who follow the rules and bear the related administrative costs and delays should not be at a disadvantage vis-à-vis those who do not.

4. The development of a global market enables businesses to produce and assemble goods in different places and to export them to many markets. Diversification of production has also increased the number of different goods available to consumers. As it is not possible to assess the conformity of all goods when they are produced or when they cross the border, market surveillance appears as a suited and necessary complement to conformity assessment for the following reasons:

(a) Cost considerations (e.g. certifications costs are high for some products).

(b) Speed considerations (e.g. lengthy conformity assessment procedures hamper the speedy placement of goods on the market).

¹ Conformity assessment is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. Conformity assessment includes activities such as: testing and inspection. This definition is taken from the document "Draft common definitions and terminology in Market Surveillance (ECE/TRADE/C/WP.6/2009/13) and adapted from ISO17000:2004, 2.1.

II. DEFINITION OF MARKET SURVEILLANCE

5. In this document, market surveillance shall be defined as:

“The set of activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in relevant legislation and do not endanger health, safety or any other aspect of public interest protection.”²

6. We distinguish between market surveillance, which is carried out by public authorities only to ensure products comply with mandatory requirements, and conformity assessment, which may be carried out by both public and private actors.

7. In general, private actors (e.g. economic operators, third-party certification schemes) are responsible for assessing conformity of products before they are placed on the market, and market surveillance authorities monitor them after they have been placed on the market. However, private actors may intervene after products have been placed on the market (through repair and other product follow-up activities) and market surveillance authorities can sometimes intervene beforehand too (e.g. through factory inspection).

III. PURPOSE OF THE GENERAL MARKET SURVEILLANCE PROCEDURE

8. The mandate of market surveillance authorities is to remove dangerous and non-compliant goods from the market. Currently, due to the increasing volume and variety of products on the market, the number and seriousness of notifications about dangerous product and the technical complexity of regulations and standards, they struggle to fulfil their mandate. Differences in surveillance practices across countries create a barrier to a fully effective system of cross-border cooperation, to the detriment of fair competition, user safety and protection of the environment.

9. One solution to this problem is to promote cooperation and harmonize market surveillance approaches internationally. This requires a new vision for an effective market surveillance system, capable of responding to the challenges of global production chains and the trend towards reducing the involvement of authorities in the pre-market phase.

10. The General Market Surveillance Procedure - outlined in this document and explained in detail in document ECE/TRADE/C/WP.6/2009/12 – is intended as a framework and guide for the establishment and operation of market surveillance based on good practice worldwide. The decision tree described in figure 1 in section IV below presents the general process and the main elements that can be addressed through inter-country cooperation to harmonize market surveillance.

² This definition is taken from the document “Draft common definitions and terminology in Market Surveillance (ECE/TRADE/C/WP.6/2009/13). It is adapted from the definition used in EU legislation (765/2008/EC, art 2 (17)).

11. If this system is to be effective in countering the proliferation of dangerous and substandard goods, it will need adequate financial resources, and a strong and shared political commitment both nationally and internationally.

IV. THREE PHASES OF THE GENERAL MARKET SURVEILLANCE PROCEDURE

12. To simplify and optimize the tasks of market surveillance authorities, surveillance procedures need to be streamlined, while allowing for sector-specific adaptations. The General Market Surveillance Procedure proposes a general model that applies to all non-food products. The tasks of the authorities dealing with the various sectors may be broken down into three phases:

- (a) Preparation of a market surveillance plan.
- (b) Execution of the plan.
- (c) Contacts with stakeholders.

13. Each phase is composed of series of actions the authorities should undertake (see figure 1). Some actions can entail multiple sub-procedures, which are presented in detail in document ECE/TRADE/C/WP.6/2009/12. The following sections explain the main steps to be taken during each of the three main phases.

A. Phase I: preparation

14. Several actors can initiate market surveillance actions, the following being the most common: Coordination Entity, market surveillance authorities; contact points; and Customs authorities:

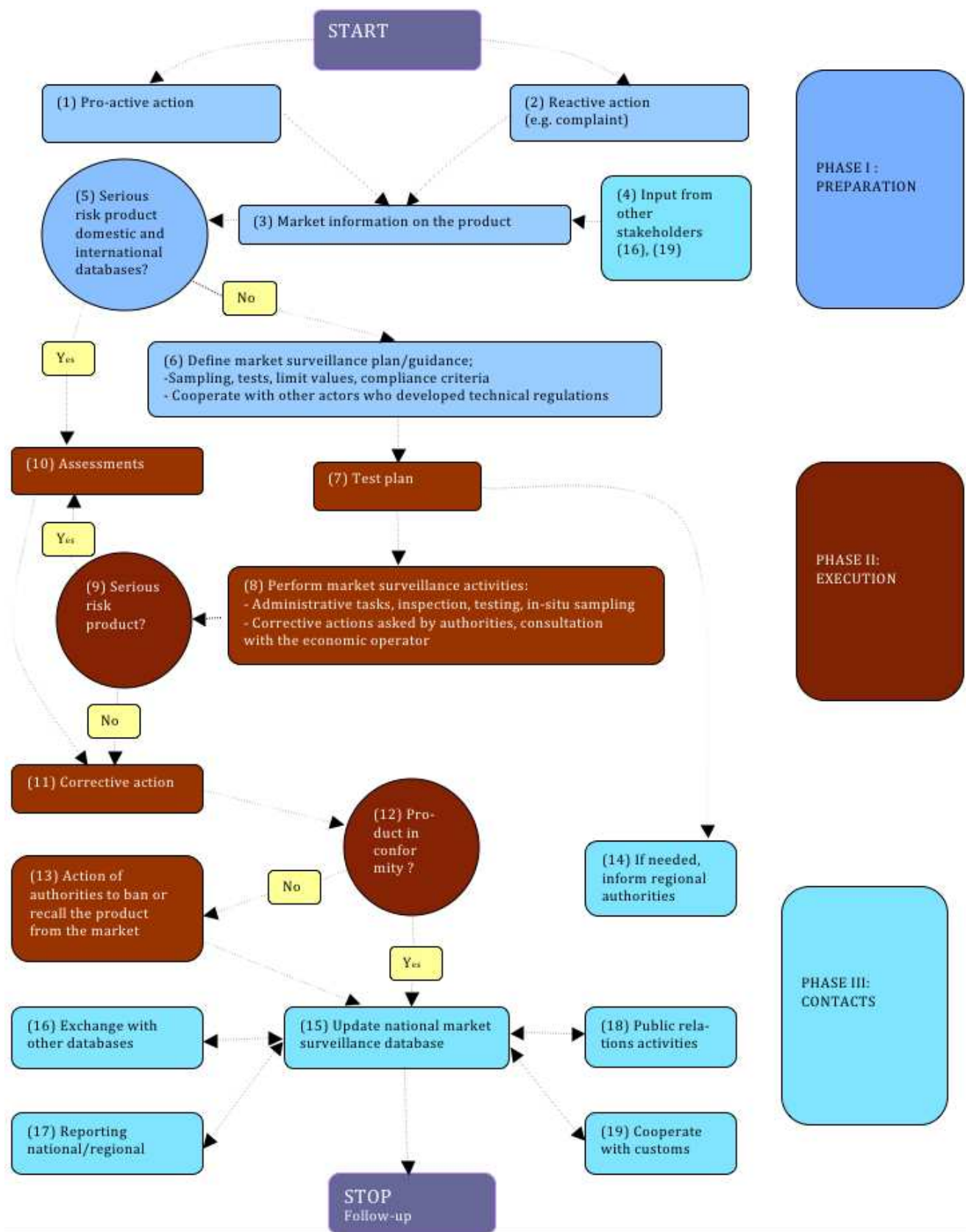
(a) Coordination Entity. Monitors surveillance activities across sectors of the food and non-food areas to build up intersectoral best practice. Given the necessary degree of specialization, the expertise remains at the level of sectoral authorities. Only certain elements of market surveillance are coordinated by this Entity.

(b) Market surveillance authorities. Responsible for planning, carrying out and following up on surveillance activities undertaken in one sector.

(c) Contact points. It is advisable to have contact points at the sector-, firm- or even at the product-level to enable fast and effective communication between public authorities and private actors whenever concerns arise about a product.

(d) Customs authorities. Have the possibility to initiate a reactive market surveillance action upon interception of substandard goods.

Figure 1: General Market Surveillance Procedure



15. Market surveillance action can be either pro-active or reactive. In the first case, it is planned based on a decision of the Coordination Entity or of market surveillance authorities, which identify priority sectors and products. In the latter case, they are complaint- or accident-driven. They can also be initiated after a substantial risk has been identified by authorities (during an inspection) or by the economic operator itself.

16. Market surveillance authorities should plan on different horizons. Long-term plans should address the overall strategy, based on the anticipated industrial, economic and political developments both nationally and internationally. Short-term plans should address more pressing issues such as the annual allocation of resources between planned activities, and their prioritization.

17. To set up their plans, the authorities must analyse risks, taking into account available information concerning these products coming from other stakeholders, as well as information about previous accidents from domestic, regional and international databases. Detailed results of these risk analyses should remain confidential to avoid damage being caused to the reputation of any sector or economic operator.

18. Two situations may arise when planning market surveillance action:

(a) If technical regulations specifying the tasks of market surveillance authorities already exist, the planning stage is simplified, as the authorities can use those criteria to carry out their activities.

(b) If such technical regulations do not exist, the authorities must first determine whether the product bears serious risk (in which case specific assessments have to be made) or not.

19. In both cases, the market surveillance authorities need to identify appropriate technical regulations so that they can assess the products and use the results of these assessments for their work. They must be able to:

(a) Perform risk assessment to determine the risk level of the product.

(b) Cooperate with other stakeholders to define appropriate technical regulations.

20. The capacity to estimate the danger represented by a product and its probability of occurrence enables the authorities to quantify risks. To set priorities, the risks need to be quantified. Although there is no general risk assessment methodology, this area is currently being developed intensively. Some standards exist and can be used to design specific risk-assessment methodologies. Below are three examples of reference to standards relevant to risk-assessment:

(a) ISO/FDIS 31000: this standard also called “Risk management principles and guidelines” applies to all sectors and covers risk identification, risk analysis, risk evaluation and risk treatment.

- (b) Other standards are limited to certain sectors:
 - Machinery (ISO 14121-2:2007, part 2)
 - Low voltage equipment (ACOS/542/INF).

21. Identifying which technical requirements apply to what product is a major task of public authorities. What rules should be followed when selecting a sample of products to check? What tests should be conducted? What parameters and values should be observed? Market surveillance authorities are often not in a position to define such guidance on their own and need to collaborate with other stakeholders.

22. Precise criteria for the work of market surveillance authorities can be developed in a number of ways, as follows:

(a) Using information other actors have gathered previously for different purposes: It may well be that technical regulations intended for producers or for third party conformity assessment already lay out criteria that can be used by the authorities for their inspections and tests. Standards and technical regulations may implicitly specify the conditions under which they can order the economic operator to undertake corrective actions or sanction it. The authorities should collaborate with the actors who developed the relevant regulations in order to understand them and act accordingly.

(b) In collaboration with other stakeholders. When no market surveillance clauses are defined (such a clause is mandatory in Common Regulatory Objectives), market surveillance authorities cooperate with the authorities who created the standard or technical rule to define adapted market surveillance requirements. The authorities may also consult with bodies designated by the authorities to select the limited assessments, which may be executed with conformity assessment bodies. These bodies also may provide a control/test plan that should be used when performing the limited tests.

23. Most of the criteria needed for market surveillance guidance are specific to a product, a range of products or to a whole sector. For sampling, different sectors have different approaches, but ongoing work might lead to the definition of common general rules.

24. Reactive actions constitute an important part of market surveillance activities and can account for up to half of the resources, and as such are essential elements in the budget and planning strategy. They are usually driven by a complaint or an accident, which requires a risk assessment analysis. Complaints and accidents can be classified into two categories:

(a) Low-risk complaints, coming from consumers in relation to minor defects in a product, or from competitors concerning unfair competition.

(b) High-risk complaints or accidents. If an accident occurs or any stakeholder informs other actors that a product represents a serious risk to health and safety or to any other justified public interest, the authorities have to perform the relevant procedure and rapidly require corrective actions or take even more restrictive measures if necessary. Because such decisions can have adverse economic consequences, they should only be taken as measures of last resort.

B. Phase II: execution

25. The second phase of the GMSP focuses on actions that market surveillance authorities have to perform to detect and deal with non-compliant products. The first step of the assessment consists in administrative tasks and visual inspections:

- (a) Does the product or equipment have a conformity mark?
- (b) Is the Declaration of Conformity present and correct?
- (c) Is the Technical File available and correct?
- (d) Is there any suspicion of non-compliance with mandatory requirements?

Speed of action. The recommended throughput time for the administrative part is 5-15 days depending on the complexity of the product and on the length of the supply chain (e.g. imported products).

26. If any suspect information is found during the first part of the assessment, the authorities may decide to test the product. Two kinds of tests exist, “checking” and “other”:

Checking. Inspectors can verify compliance with requirements of basic product properties (measurement of dimensions, basic electrical quantities, etc.).

Other. These require specific equipment/infrastructure usually only available to accredited conformity-assessment bodies or similar (electromagnetic compatibility, radio-communication test equipment, etc.). If the market surveillance authorities cannot perform such tests, they should collaborate with conformity assessment bodies to assess the conformity and risk level of the suspected products.

Speed of action. The recommended throughput time for the testing part is 10-20 days depending on the complexity of the product and the number of essential requirements assessed/tested.

27. If the non-compliance detected by the authorities does not pose an acute safety risk, the third step consists in holding a consultation with the economic operator. The authorities will subsequently ask the operator to solve the non-conformity issue within a defined period of time in this process, MSAs shall:

- (a) Communicate without delay to the economic operator the corrective measures that must be taken.
- (b) Inform the economic operator of the remedies available under the law of the member State.
- (c) Inform the economic operator of the time limits to which such remedies are subject.

Speed of action. Ten days should be given to the economic operator to propose appropriate measures to ensure compliance; and five additional days for the authorities to decide what corrective measures might need to be taken.

28. Should the situation be an urgent one (health, safety or other grounds relating to the public interest), the consultation with the economic operator must be postponed to avoid dangerous products' being disseminated. A rapid assessment must be made so as to take corrective action immediately and bring the product into conformity with requirements. If the economic operator has failed to implement corrective action or if this proves to be insufficient, market surveillance authorities can take measures to ban a product, or as a means of last resort make a recall to withdraw it from the market.

C. Phase III: contacts

29. The third phase is closely intertwined with the two first because consultation and rapid communication with other stakeholders is necessary in order to prepare optimal market surveillance plans and minimize safety risks. Market surveillance authorities should remain informed and keep other actors informed through:

(a) Institutional channels of communication (e.g. contact points, other market surveillance authorities, Coordination Entity, conformity assessment bodies, standardization organizations, regional organizations).

(b) Exchange of information between domestic, regional and international market surveillance authorities' databases.

(c) The media (mostly in case of recall actions and awareness campaigns).

30. In the preparation phase, market surveillance authorities can build on existing information. The use of statistics from various databases on dangerous goods and on the frequency of occurrence of accidents is key to prioritizing target sectors and products for market surveillance action. Here, too, the support of other actors involved in the definition of standards and technical rules is necessary in cases when no criteria exist for market surveillance activities. Once the authorities have discovered a product that poses a serious risk, they should immediately inform partner institutions in their own country and region.

31. If corrective action bring a product back into conformity with mandatory requirements, market surveillance authorities should update their database, exchange this information with other databases and inform their domestic and regional partners, as well as Customs.

32. The market surveillance authorities also need to better use the leverage of media to raise public awareness of important issues. Until now, the various media have mainly been used to inform the public of acute risks and of recall actions (e.g. cars, toxic toys). However, the authorities could also work with the media to sensitize the public to the necessity to harmonize

standards, improve the traceability of products, etc. Increasing the visibility of the work of market surveillance authorities might greatly help to ensure that more resources are devoted to this important task.

33. Once all these steps have been taken, the surveillance authorities should follow up on non-compliant products to check if economic operators have correctly implemented the required changes. The follow-up market surveillance action should be done within a reasonable period of time (generally one year).

V. DIRECTIONS FOR FUTURE WORK

34. The GMSP should be understood as an integral part of the activities of the Working Party on Regulatory Cooperation and Standardization Policies (WP.6). WP.6 started work on market surveillance issues in 2002 with a first international forum, followed by three others in 2005, 2007 and 2008³. These events, which were attended by over 100 representatives from over 30 countries, as well as the European Commission, the Eurasian Economic Community (EurAsEC), the World Intellectual Property Organization, the World Trade Organization, the European Committee on Standardization (CEN), the International Organization for Standardization (ISO) and numerous business executives, were organized against a background of growing commitment both by the authorities and by business to an efficient market surveillance system that could ensure that products fulfil mandatory requirements without endangering users, consumers or the environment and maintain fair competition.

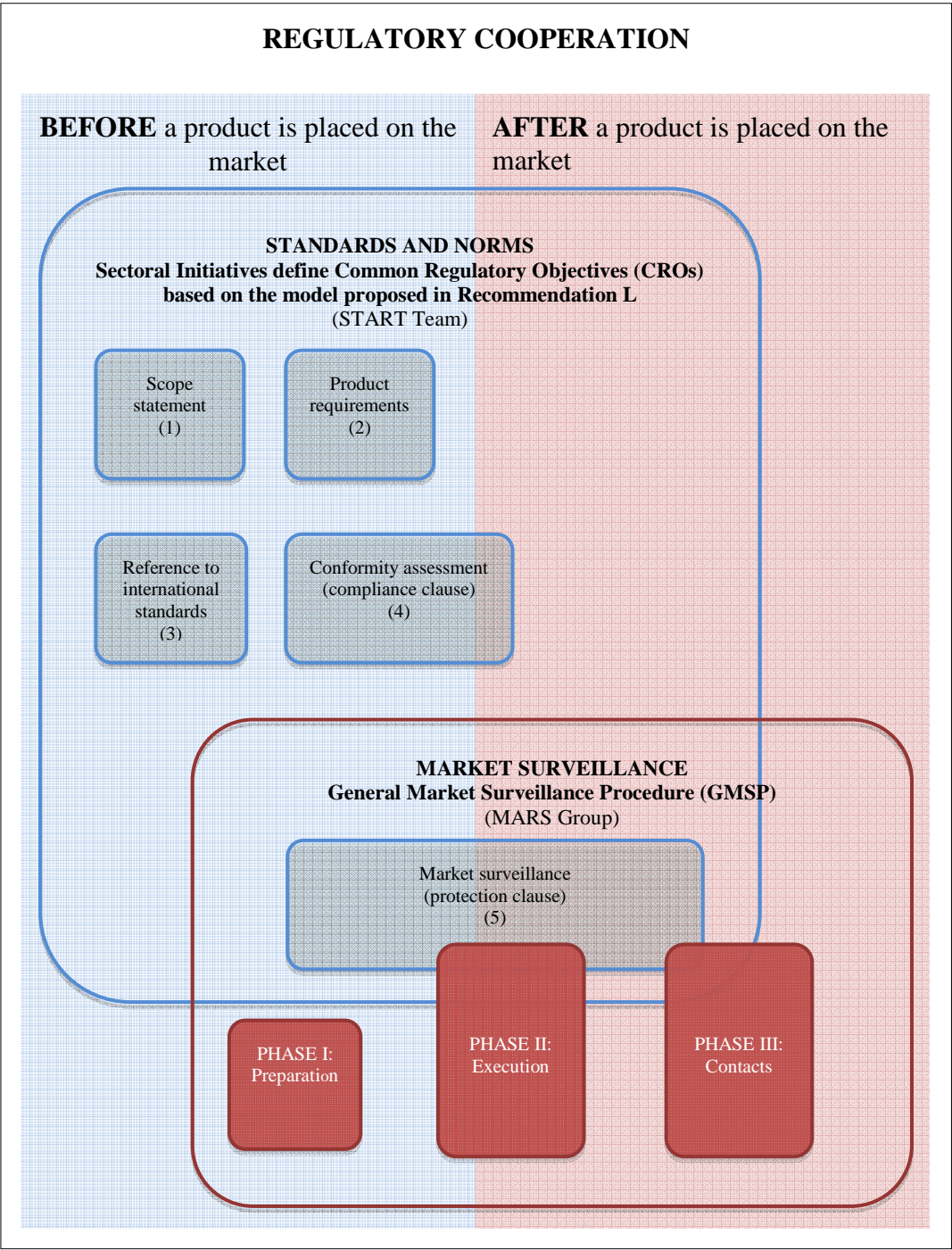
35. These activities are monitored by the Advisory Group on Market Surveillance (MARS) and also resulted in the adoption, in 2007, of Recommendation M on the “Use of Market Surveillance Infrastructure as a Complementary Means to Protect Consumers and Users Against Counterfeit Goods”⁴ which pioneers a novel approach in the fight against counterfeit goods, notably through the involvement of market surveillance authorities and intellectual property owners.

36. Although market surveillance is a task on its own, it is intertwined with and builds on elements decided over by other actors defining standards and regulations. The broad approach the Working Party takes on regulatory cooperation integrates market surveillance, as well as metrology, standards and norms, and conformity assessment. This integrative approach is necessary, because all stakeholders need to be consulted in order to develop tools able to strengthen regulatory cooperation and facilitate the work of market surveillance authorities.

³ First Forum on Market Surveillance (29 October 2002, Geneva, Switzerland), see: http://www.unece.org/trade/wp6/documents/2002/2002_Forum.html; Second International Forum on Market Surveillance and Consumer Protection (24-25 October 2005, Geneva, Switzerland), see: http://www.unece.org/trade/wp6/documents/2005/2005_Forum.html; International Seminar on Product Safety and Counterfeiting (5-6 November 2007, Geneva, Switzerland), see http://www.unece.org/trade/wp6/documents/2007/2007_Seminar.html; Panel Session on Market Surveillance Model Initiative (4 November 2008, Geneva, Switzerland), see: <http://www.unece.org/trade/wp6/documents/2008/panel1.htm>.

⁴ See <http://www.unece.org/trade/wp6/Recommendations/Recommendations.html>

Figure 2. Relation between two important areas and tools of the Working Party:



37. The other main strand of the Working Party's activities, the Sectoral Initiatives currently monitored by the START Team, illustrates this global approach to regulatory cooperation.⁵ Sectoral initiatives are based on a model set out in Recommendation L, at the core of which is

⁵ Sectoral Initiatives on (1) Telecom (2) Earth-Moving Machinery (3) Equipment for Explosive Environments and (4) Pipeline Safety.

the concept of Common Regulatory Objectives. For each sector, these objectives address legitimate Government concerns related to public health, safety or protection of the environment. They specify elements listed below (also see figure 2), which are key to converge towards a common regulatory framework:

- (1) Scope of the initiative (the products to which it applies).
- (2) Product requirements (performances the product must achieve).
- (3) International standards that should be referred to in national legislation.
- (4) Conformity assessment procedures that will be mutually recognized.

(5) Market surveillance, the sector-specific content of assessment procedures (indications on what standards to use to assess compliance, withdrawal conditions, alert procedures, etc.).

38. Activities monitored by the MARS Group and the START Team are complementary in the promotion of regulatory cooperation and convergence towards international standards and best practice. For example, to implement requirements set out in Common Regulatory Objectives, international standards and specific national rules, market surveillance authorities need to collaborate with other stakeholders and devise an efficient strategy. So in the continued development of the GMSP, the collaboration of the sectoral initiatives will be of utmost importance.

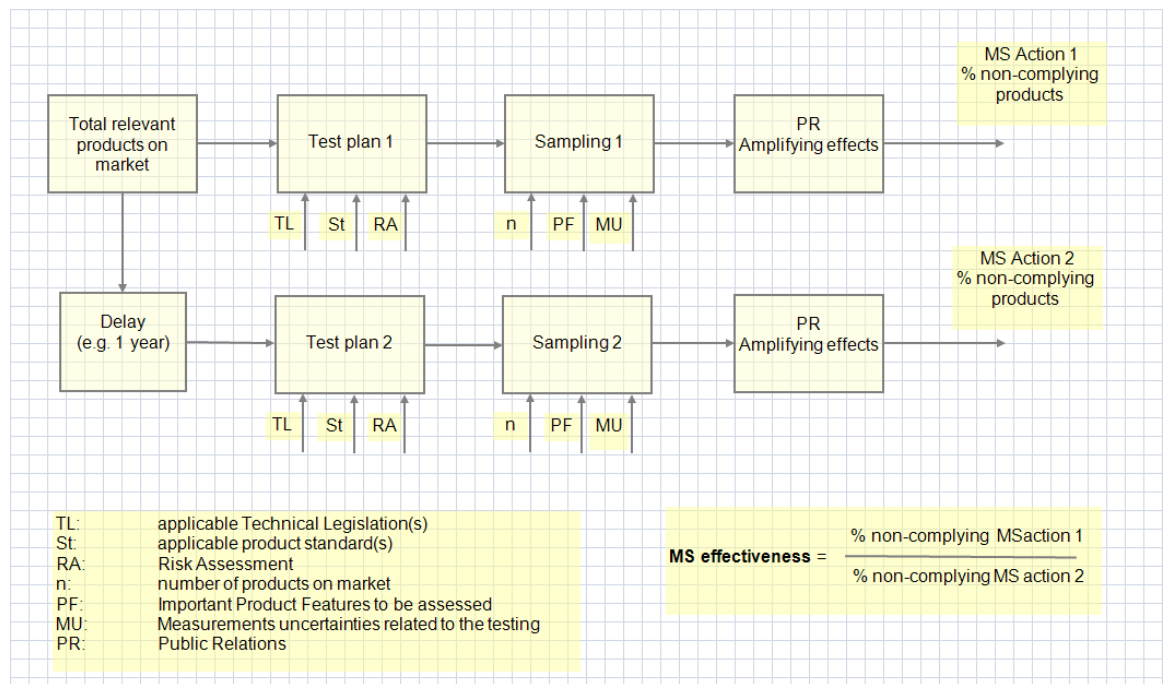
39. Work on the GMSP is still ongoing, comments and appropriate feedback are necessary to improve and generalize the procedure.⁶ Many elements need to be further developed, among them:

(a) Quantitative models to help market surveillance authorities assess the effectiveness of their activities (figure 3 presents a general idea that could be further developed).

(b) Tools of risk assessment and management tailored for market surveillance authorities.

⁶ Although the GMSP is formulated in a general way, it has been influenced by existing practice (mostly European Union), and in particular draws on experience gained in the sector of electrical household equipment.

Figure 3. Measuring effectiveness of market surveillance activities



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