UNITED NATIONS

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Distr.
GENERAL

ECE/TRADE/C/WP.6/2008/11
29 October 2008

ENGLISH ONLY

Economic and Social Council

ECONOMIC COMMISSION FOR EUROPE

COMMITTEE ON TRADE

Working Party on Regulatory Cooperation and Standardization Policies

Eighteenth session
Geneva, 3-4 November 2008
Item 8(a) of the provisional agenda

MARKET SURVEILLANCE

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

Report of the Advisory Group on Market Surveillance, its activities and its meeting in Bratislava, 2-3 October 2008

Note by the secretariat

Summary

At its thirteenth session, the Working Party established an Advisory Group on Market Surveillance ("MARS" Group) and mandated it to report on its activities (see TRADE/WP.6/2003/16 para. 116).

This document contains a report of the "MARS" Group on its sixth session held in Bratislava on 2 and 3 October 2008 at the kind invitation of the Government of Slovakia and is submitted to the Working Party for approval.

I. INTRODUCTION

1. The President of the Slovak Office of Standards, Mr P. Lukac, Vice Chairperson of the United Nations Economic Commission for Europe Working Party on Regulatory Cooperation and Standardization Policies (WP. 6) welcomed participants and opened the meeting by highlighting the impressive economic performance of Slovakia in the past year.

2. The Chairperson of the Working Party, Mr. C. Arvius, Director Internal Market of the Swedish National Board, thanked the Slovak Office of Standards for organizing the meeting and the UNECE Secretariat for its preparatory work.

3. The Acting Secretary of the UNECE WP. 6, Ms. L. Jachia, placed the meeting in the context of the activities of the Working Party, which spanned the whole product life cycle from regulatory cooperation to assessment of conformity to market surveillance.

4. Participants were then invited to present themselves and the institution that they represented. Most of the participants came from market surveillance authorities, national institutes of standardization, Ministries of Trade and of Economy, as well as from authorities responsible for labour inspections. A detailed list of participants can be found on the WP. 6 website.

II. THE EUROPEAN UNION NEW FRAMEWORK

5. The Directorate-General on Enterprise of the European Commission, Ms. R. L'Abbate, of the Directorate-General Enterprise and Industry of the European Commission and Ms. K. Steinlova, Head of the European Union Affairs Department of the Slovak Office of Standards, Metrology and Testing, presented the new legislative framework of the European Union.

6. Currently, the effectiveness of market surveillance activities is widely disparate across the 27 European Union Member States. The proliferation of unsafe and counterfeit products on the markets and the ensuing distortion of competition is damaging and should be stopped. The new framework has therefore been introduced to provide a common definition of key terms, such as economic operators and the principle of mutual recognition, and complete it by providing a framework for the marketing of goods, specifically regarding accreditation and market surveillance.

7. The relevant legislative texts that laid out the New Framework were:

(a) Regulation N° 764/2008 on the application of the mutual recognition principle

(b) Regulation N° 765/2008 on requirements for accreditation and market surveillance

(c) Decision N° 768/2008 on a common framework for the marketing of products

8. These texts were adopted on 9 July 2008. The regulation 764/2008 will enter into force on 13 May 2009, while regulation 765/2008 will enter into force on 1 January 2010[1].

9. Text 768/2008 is a decision which will be used for future legislation, while regulation 764/2008 and 765/2008 are immediately applicable from the time of their entry into force. Both instruments were necessary so that the regulations cover new ground not covered by current legislation, while the decision covers elements that are already covered by the legislation, and areas in which specific sectors will be allowed to deviate according to their specificities.

III. MARKET SURVEILLANCE

10. Under Reg. 765/2008, market surveillance is defined as the activities carried out and measures taken by public authorities to ensure that products are in compliance with legal requirements set out in the relevant Community harmonisation legislation or do not endanger health, safety or other issues of public interest protection. It applies to all products excluding food and feed, in so far as there are no specific provisions with the same objective in Community harmonization legislation (see Article 15/2 of 765/2008).

11. National authorities are also allowed to take more specific measures, under the General Product Safety Directive (GPSD) which addresses consumer products (available at http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm#gpsd).

12. The regulation provides that Member States put in place a number of measures to ensure that market surveillance activities are properly organized and carried out. In particular, Member States will:

(a) Establish appropriate coordination mechanisms among national authorities

(b) Establish adequate procedure to manage non-compliance

(c) Establish general and sectoral programmes

(d) Ensure that market surveillance authorities have necessary powers and resources

13. Market surveillance authorities should in particular be enabled to perform appropriate checks on an adequate scale, enter the premises of economic operators, destroy unsafe products or otherwise make it impossible to market them.

14. Economic operators will also have precise obligations, which relate to their role in the supply and distribution chain. All the economic operators will be required to be able to supply the market surveillance authorities with information regarding operators that have supplied them with a product or to whom they have supplied a product. In addition:

(a) The manufacturer - who has detailed information on the product design and of the productive process – will be responsible for conformity assessment

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[1] All texts are available online at http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:218:SOM:EN:HTML

(b) The importer will be responsible for ensuring compliance of imported products and in particular he needs to ensure that the third country producer has carried out conformity assessment, produced the relevant documentation. He also needs to ensure that the product bears the conformity mark and that the importer's name and address is indicated

(c) The distributor of products produced within the community needs to ensure the presence of conformity marking and required documents

IV. MUTUAL RECOGNITION

15. Although mutual recognition is a funding principle of EU law and jurisprudence, until now the general perception was that national rules always prevailed. Both businesses and administrations are not sufficiently aware of the scope of the application of the mutual recognition principle and of the burden of proof.

16. In particular, businesses often choose to engage in dialogue with the administration of the Member State of destination because it is difficult for them to know if, how and when mutual recognition will be applied. Also, the lack of a common address book results in insufficient dialogue among competent authorities.

17. The Mutual Recognition Regulation (EC) N° 764/2008 radically changes the status quo by providing that the denial of mutual recognition should be the exception and not the rule. The regulation introduces precise procedural requirements in case of denial of mutual recognition:

(a) Whenever a member state intends to adopt decision to deny mutual recognition, it will send written notice to the economic operator concerned, specifying the technical rule and setting out technical or scientific evidence that the intended decision is justified by overriding reason of public interest and that no less trade-restrictive measure can be taken. The intended decision must be based on the characteristics or type of product.

(b) The economic operator can then submit comments within a time limit set out in the written notice.

(c) Further to the assessment of comments received, if any, the public authorities will take their decision and immediately inform the economic operator concerned. The authorities should provide technical or scientific justification for their decision, on the grounds of Article 30 or mandatory requirements recognised by the European Court of Justice.

18. The scope of the regulation is very wide. All products are covered <u>except</u> for:

(a) Products covered by lex specialis (e.g. railroad equipment)

(b) The withdrawal of dangerous products under the General Product Safety Directive

(c) The withdrawal of food and feed in order to protect human health and requiring rapid action

19. Another important provision is that each Member States must designate at least one Product Contact Point – which can be a new or existing private or public body – that will be responsible for:

(a) Providing technical rules applicable to a specific type of product in that Member State

(b) Advising whether the product is subject to prior authorisation

(c) Giving contact details of the competent authorities

(d) Describing remedies generally available in the national territory in the event of a dispute between competent authorities and economic operators

20. The Director of the International Cooperation and EU Integration Department of the Bulgarian State Agency for Metrological and Technical Surveillance, Ms. V. Panayotova, observed that mutual recognition under 98/34 was equivalent to recognizing the functional equivalence of a technical regulation. In the context of this new regulation, mutual recognition is a different concept.

V. CONTROL OF PRODUCTS ENTERING THE COMMUNITY BY THE CUSTOMS AUTHORITIES

21. An important part of the market surveillance activities are carried out by the customs authorities that release products from third countries on the market of the European Union for free circulation.

22. The Regulation N° 765/2008 lays down a number of provisions for the proper organization of these activities. In particular, customs authorities should have the powers and resources necessary for the proper performance of market surveillance tasks, and they should carry out appropriate checks on the characteristics of products on an adequate scale.

23. If products are found to present risks, or they are not accompanied by the relevant documentation, or they bear a misleading CE marking, customs authorities may suspend the release for free circulation. In such a case, they are required to inform the market surveillance authorities that then take the final decision on the goods' release.

VI. "CE MARKING"

24. The legislator saw a need for clarification on the use and meaning of the CE mark and its role versus other conformity marks.

25. Decision 768 clarifies that CE is the only conformity mark. The decision also lays down the rules and conditions for its affixing and specifies the role of the market surveillance authorities in ensuring its correct implementation.

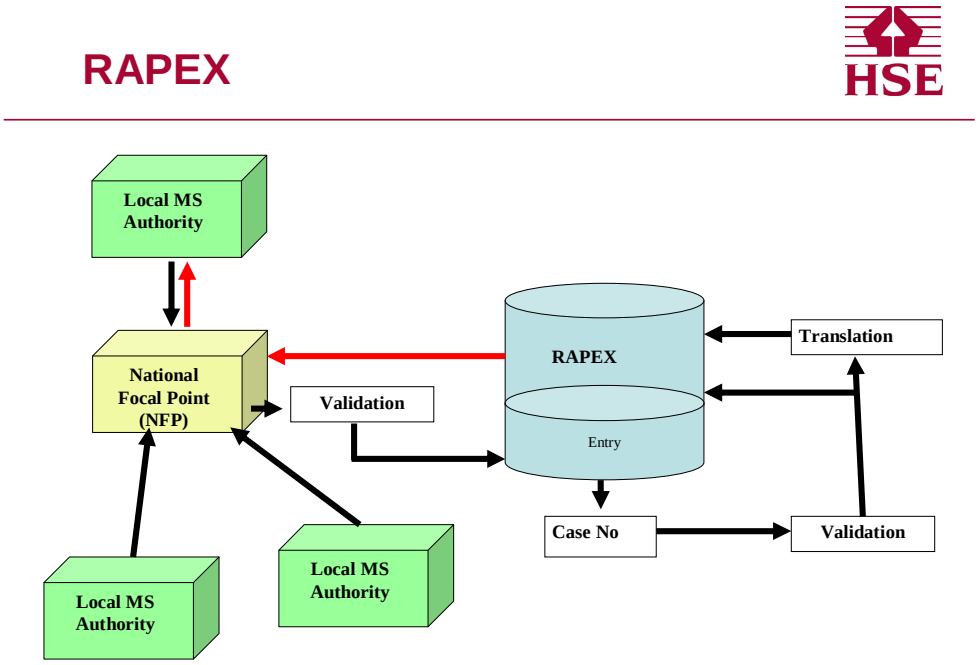
VII. THE INTERNET-BASED INFORMATION AND COMMUNICATION SYSTEM FOR MARKET SURVEILLANCE

26. The Head of the European Union Affairs Department of the Slovak Office of Standards, Metrology and Testing, Ms. K. Steinlova, made a detailed presentation of the Internet-based Information and Communication System for Market Surveillance (ICSMS).

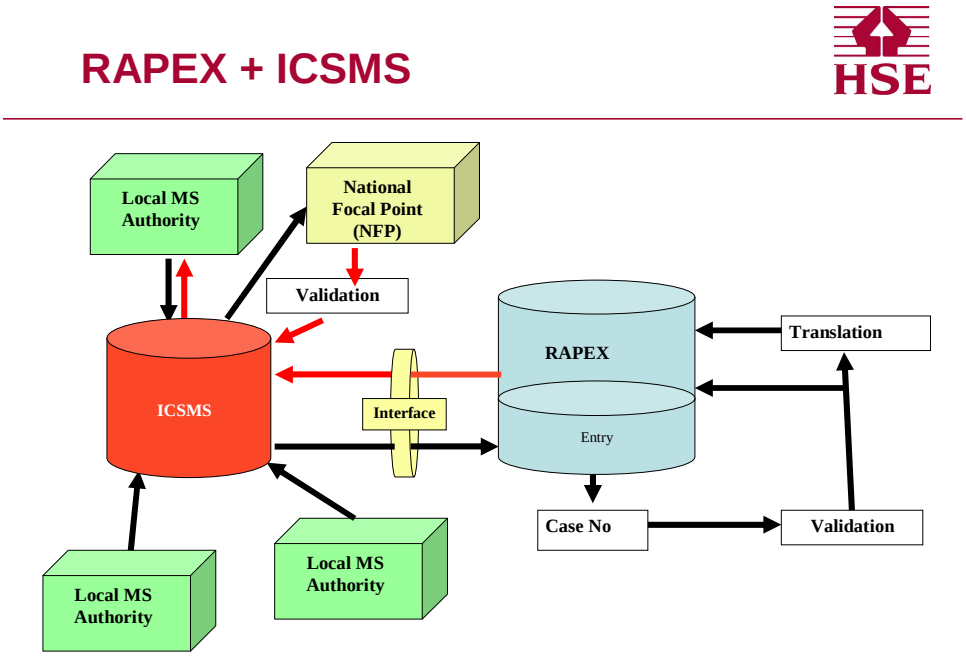
27. She explained that currently, two systems coexist for the exchange of information among market surveillance authorities and between authorities and consumers in the non-food sector:

(a) The rapid information exchange (RAPEX)

(b) The ICSMS system



28. RAPEX applies to consumer products with a serious and immediate danger. When a product is found to be dangerous, and risk is not restricted to the national market, the competent national authority informs the National Focal Point (NFP), which informs the European Commission. If the Commission validates the request, then it is registered in RAPEX, which disseminates the information to the other NFPs. The NFPs then transmit it to the national market surveillance authorities. The Commission also publishes weekly overviews on the internet of dangerous products and the measures taken to eliminate the risks.



29. The ICSMS system has a broader scope which includes general information as well as details on detected non-conformities. It allows for a direct and immediate exchange of information among the market surveillance authorities. Currently, the following countries are using ICSMS: Austria, Belgium, Cyprus, Estonia, Germany, Luxemburg, Malta, Slovenia, Sweden, Switzerland, The Netherlands and United Kingdom. There are plans to make the two systems interoperable, so that the information could be entered only once, as shown in the graph below.

30. Regulation 765/2008 foresees the continued use of RAPEX for products presenting a serious risk and foresees that the system be extended to include professional products (see Article 22) It also (art. 23) foresees the development of a general system for the exchange and archiving of information concerning market surveillance activities which. For this purpose, the ICSMS system could be extended to the countries that are not currently participating and reinforced. Another option would be to develop a new system from scratch.

VIII. REPORT OF THE MEETING OF THE SENIOR OFFICIALS GROUP ON STANDARDS AND CONFORMITY ASSESSMENT POLICY (SOGS) OF 1 OCTOBER 2008

31. The main results of the meeting of the SOGS Group held on the previous day and which had addressed the options for the development of IT systems of exchange of information among the market surveillance authorities of the EU were presented.

32. A list of questions left open for the members' comments follows.

(a) Should this system be limited to informing its members of national measures concerning serious risks only?

(b) Should this system be designed as a tool for both national authorities and consumer information, or should the general database under Article 23 ensure this information and become the only information point open to consumers?

(c) Are there any elements that are not present in the model RAPEX organization which would need to be considered to organize the rapid information exchange mechanism under the Regulation, and if so, what?

(d) Does the broad scope of the system presented under the Regulation justify more than one contact point per Member State, and if so, what structure would be the most workable?

(e) Should the notification procedure under the Regulation be organized in a different way than the model notification procedure used currently in RAPEX, and if so, how?

(f) What supplementary information needs to be added to the notification forms which are currently used in RAPEX?

(g) How can it be ensured that notifications sent under the Regulation reflect the final decision on a specific notification? In other words, should the measures notified under the Regulation within a reasonable delay be reviewed to update the status of the notification (e.g. deleted, withdrawn, in progress, etc.)?

(h) How can the information flow on products between market surveillance authorities and customs and between customs themselves be enhanced?

(i) How should the notification process, as requested in the Regulation, be organized at national level?

(j) What are the training and other capacity-building needs of the participating authorities?

IX. THE IMPLEMENTATION OF THE EUROPEAN UNION MARKET SURVEILLANCE FRAMEWORK: THE EXPERIENCE OF THE UNITED KINGDOM

33. The United Kingdom has a comprehensive but very diverse system for market surveillance (e.g. there are 202 local authorities trading standards departments and these bear only a part of the general market surveillance responsibilities). In this context, the implementation of the EU new framework will require informing the EU and the consumers about the respective responsibilities of the market surveillance authorities and establishing effective coordination among them.

X. RESPONSIBILITIES OF LABOUR INSPECTIONS BODIES REGARDING MARKET SURVEILLANCE

34. Labour inspection bodies have wide and important responsibilities regarding market surveillance, which are laid out in several legislative acts. One of the most important tasks of these inspection bodies is to ensure that employers provide for work equipment that does not threaten the safety and health of workers. In fulfilling this task, the bodies cooperate actively with a number of institutions, including the market surveillance authorities.

35. The new Regulation N° 765/2008 significantly reinforces the role of labour inspection bodies in relation to market surveillance. In order to implement the regulation, a number of actions will be necessary, in particular: (i) legislative measures; (ii) provisions for strengthening of labour inspection bodies' competence in the market surveillance field; (iii) organizational measures; (iv) increased cooperation with other institutions and (v) investments in information technologies.

XI. THE UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE GENERAL MARKET SURVEILLANCE PROCEDURE

36. The Convener of the General Market Surveillance Procedure (GMSP) presented the initiative in detail. The objective of the work which is underway under the umbrella of the UNECE MARS Group is to provide assistance to market surveillance authorities worldwide by developing a general decision tree model that can be used in the implementation of specific national or regional regulations.

37. The model was based on original work by the Convener in 2006, which he had substantially extended and updated in 2008 specifically for the MARS working group. The purpose of the presentation was to explain the model in detail so that it would be well understood by all the groups' participants. The model was not yet a final document, but needed the inputs of a working group of academia, government authorities and experts.

38. The model mirrors the activities of the market surveillance authorities and is therefore organized in three phases: (i) the preparatory phase; (ii) the execution phase and (iii) the stakeholder's contact phase. Each of these phases has a number of sub-procedures which describe in detail all the actions that the authorities must undertake.

39. The convener had also developed two questionnaires which set out to probe the GMSP and verify how adequately it describes the actual work of the MSA. It has been very difficult to get answers to the questionnaire because of the time it takes to answer.

40. Finally the Convener raised two open research questions:

(a) If a heterogeneous number of products is on the market and if a limited sampling plan is used, how sure are we that the market surveillance actions undertaken are appropriate?

(b) Considering the distribution as described in research question 1, how can we model the effects of risk assessment, measurement of uncertainty, sampling schemes, visibility, and its effect on effectiveness?

41. Some of the participants expressed the view that it would be better to divide the questionnaire into two parts, the harmonized and non-harmonized area. However, the Chairperson of the UNECE Working Party 6 clarified that the initiatives developed by the MARS Group, a United Nations body, need to be relevant for all United Nations Member States. The distinction was not relevant for non-European Union member states. Participants felt that the model should serve to verify the adequateness of the actions undertaken by the market surveillance authorities worldwide, but could subsequently be adapted to national and regional needs.

42. The model had been the subject of several meetings among the specialized market surveillance authorities in Slovakia and some presented their detailed comments. One of the participants observed that in the context of cosmetics, when the country from where the products come from is obliged to send the documents along with the product, the procedure as described in the GMSP could hold. However, when the product comes from another member state, the documentation does not need to be sent and if there is a need to check the documentation, then this takes longer than the 15 days foreseen by the model.

43. The discussion then turned to the questionnaires that the Convener had prepared to verify the applicability of the GMSP in actual practice. Participants raised the following points:

(a) The statistical approach should be entirely redefined

(b) The stakeholders addressed by the questionnaire were not clearly defined (conformity assessment bodies, notified bodies, inspection bodies ....)

(c) A problem existed concerning confidentiality of information

(d) It was difficult to ascertain the budget of the market surveillance authority because in many countries and many sectors, market surveillance was one among several functions performed by one single administrative body

(e) The questionnaire would need to be tailored to specific sectors because specific procedures existed in the different sectors.

(f) In Slovakia, this work had already started: a meeting had been held to consider the questionnaire and then the questionnaire was sent to the head of all the bodies responsible. Some answers had been received and others were being prepared. Work was underway to single out the common aspects among the answers received.

XII. CONCLUSIONS AND FOLLOW-UP

44. Participants then agreed on the following follow-up actions. The MARS Group:

(a) Requests the UNECE Working Party 6 to adopt the decision that all UNECE Member States are required to send to the secretariat an updated list of the market surveillance authorities in the different sectors.

(b) Requests the Bureaux of the Sectoral initiatives underway (Sectoral Initiative on Equipment for Explosive Environment, Telecom Initiative and Earth-moving machinery initiative) under START to provide their comments on the draft model, and see how well it is suited to their specific sectors of activity.

(c) Decides to suspend the administration of the questionnaire for the time being and, at a later stage, develop questionnaires targeted to specific sectors.

(d) Requests the UNECE secretariat to develop an introduction to the procedural document and present a first draft of the document to the 2008 November session of Working Party 6. The work on this document would continue after the session in coordination with an ad hoc working group.

(e) Requests the Convener of the GMSP Initiative to develop a general document on market surveillance which explains what it is in simple terms for the 2009 WP. 6 annual meeting, in coordination with an ad hoc working group.

(f) To resume the work on common definitions and terminology initiated by the sub-group on Market Surveillance Definitions. In this regard, there was a need to find a new coordinator for the work. The definitions contained in the EU regulations would need to be reflected in the work.

45. All participants agreed to send to the UNECE secretariat any reference to existing documents which could assist the Convener or the Secretariat in developing the documents.

46. Participants also agreed on the following responsibilities for continuing the work:

(a) Bulgaria and Belarus would consider taking responsibility for the continuation of the work on definitions (see point 44.(f))

(b) Macedonia would consider the possibility of taking responsibility for the coordination of the work on the procedural document (see point 44.(d))

(c) Romania would consider the possibility of taking responsibility for the coordination of the work on the general document (see point 44.(e))

47. In closing the meeting, the Chairperson of the UNECE Working Party 6 thanked the participants for their presentations and active role in the debate, and the organizers for the very warm hospitality.

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