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REGULATORY COOPERATION AND STANDARDIZATION POLICIES

Questions from the Russian regulatory authority and preliminary replies

Note by the secretariat

In 2007, the Working Party on Regulatory Cooperation and Standardization Policies received a request for information from the Russian Federation on regulatory practices. This request was presented to the Team of Specialists on **ST**andardization **And** **R**egulatory **T**echniques (“START” Team) at its March 2007 meeting. Two participants in the “START” Team have provided initial replies.

The questions and replies are reproduced in this document which is submitted for information and for further contribution or comments from delegations to the Working Party and also to the Committee on Trade and as a background document for the symposium on “Trade rules, regulations, and standards: different levels of rulemaking and their impact” to be held at Geneva on 23 October 2007.

* ECE/TRADE/C/2007/1.

I. INTRODUCTION

1. At the UNECE International Forum on a Common Regulatory Language for Global Trade (June 2006), good regulatory practices were debated. Subsequently, contacts with Russian regulatory authorities were established and their representatives took part in the meeting of the Team of Specialists on Standardization And Regulatory Techniques (“START” Team) held in Geneva, in March 2007. During this meeting, the “START” Team noted the importance of identifying and promoting good regulatory practices and approaches among interested UNECE member States and agreed to assist Russian regulators in finding potential solutions to current practical problems related to the preparation and implementation of technical regulations in the Russian Federation.
2. Following this meeting the participants from the Russian Federation submitted to the UNECE a set of questions which were then distributed to “START” Team participants. The UNECE secretariat received preliminary replies from the European Commission (EC) experts (their replies do not constitute an official EC position on issues raised) and comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”) relating to the Working Party’s project in that area.
3. The paper is structured in the following way. Each group of questions (There are six of them) is followed by answers/comments from the European Commission (EC) and then from the Chair of ISO/TC 127. The questions and answers are reproduced in the form and language received by the secretariat.

II. QUESTIONS FROM RUSSIAN REGULATORY AUTHORITIES TO WP.6 EXPERTS, AND ANSWERS/COMMENTS FROM THE EUROPEAN COMMISSION AND THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

A. Group 1 - Standards in technical regulations

1. Overview (regulatory task)

4. Development of harmonized standards, the implementation of which can be used on a voluntary basis for the confirmation of the requirements in technical regulations (practice at EU: initially a bid list (mandate) for the development of harmonized standards is formed, then based on the results of the development of such standards and the determination of the extent of their harmonization, they are included in the list of the European Commission).
5. In Russia a technical regulation (TR) can be developed by any person, a group of companies or a State agency and be brought into the legislative assembly (i.e. parliament; for adoption) by a member of such an initiative group, or it can be adopted by the Government of the Russian Federation or by the President.

2. Questions

Question 1:

6. In what period is a draft list of the harmonized standards to be developed, established? (Namely, on the basis of the draft technical regulation (TR)/directive or on the basis of already approved directive/TR?).

7. Who forms such list and at whose suggestion? Namely, the State body, which approved the directive/TR or the developer of the initial project of a TR (directive)?

Question 2:

8. What are the procedures and the order of work (its organization), including the preparation of the technical task (mandate) for a new harmonized standard?

9. Who is involved in this process? (who is doing the work and how?) For example, who is responsible for preparing the mandate for a standard and who is responsible for developing the standard?

3. Replies from the European Commission

To question 1 (see paragraphs 6 and 7 above):

10. Harmonized standards are developed by the European Standards Organizations following requests ("mandates") given to them by the Commission on the basis of article 6 of Directive 98/34/EC. The list of harmonized standards to be prepared by the European Standards Organization according to such mandates is, on a practical basis, established via two possible ways: (a) by the services of the Commission themselves, based on their own knowledge of the needs of standards necessary to support the implementation of the directive; and (b) by the European Standards Organization (ESO). In the last case, the Commission first allocates a programming mandate, requesting the ESOs to propose a list of harmonized standards to be developed. This list is screened by the Commission and is the basis for the allocation, in a second step, of a standardisation mandate. The final choice of harmonized standards to be included in the mandate remains a decision of the Commission services. The draft list of harmonized standards is generally prepared in parallel to the development of the directive, but after the draft directive has reached a certain stage of maturity. It may also be developed after the final approval of the directive, although, for timing reasons, this is generally not the favoured option.

To question 2 (see paragraphs 8 and 9 above):

11. The draft mandate is first discussed between the Commission and Member States, before it is officially given to the ESO, which then dispatches it to their national members, i.e. the National Standards Organizations. After discussion, the mandate is generally accepted by the

ESOs, on behalf of their national members. This acceptance signals the start of the standardisation work that will result in European standards. At this point in time, all national standards organizations have to stop their work on the subjects covered by the mandate, and dedicate their contribution to work at European level, in Technical Committees. These European Technical Committees, created by the ESOs, are made up of national delegations, sent by their parent national standard body, and consist of a balanced representation of industrials, public authorities, consumers, and all other interested parties. Once a consensus is found within the European technical committee, the draft standards are submitted to the formal approval procedures (public enquiry and formal vote) before being officially approved. Their titles are then published in the official journal of the European Union.

4. Comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”)

To question 1 (see paragraphs 6 and 7 above):

12. Standards are used to define the technical requirements for many countries. Sometimes standards are referenced in regulations and for some requirements the standards are used as voluntary requirements without specific regulations. In general, harmonized standards to support the technical requirements of a TR need to be available in time for manufacturers to use them in order to comply with the TR. Using existing standards, such as ISO standards, as the basis for national harmonized standards is a good way to facilitate the development of national standards. Some ISO Committees develop standards to address potential needs for regulations and even try to anticipate future needs for standards to support regulations. As an example, ISO/TC 127 for Earthmoving machinery has as its objective to develop and maintain a complete set of ISO standards to address all safety risks and all other needs for standards. ISO/TC 127 has members who represent health and safety organizations, regulatory organizations, machine users, and manufacturers. The expertise in this group exceeds the expertise in a single member country, so the ISO/TC 127 standards can be better than standards that are nationally developed. Using ISO standards as national standards helps national manufacturers meet both national requirements and the international requirements for exporting machines to other countries.

To question 2 (see paragraphs 8 and 9 above):

13. The Vienna Agreement defines a procedure for the EU standards organization to work with ISO to develop EN/ISO standards for the EU that are the same as the ISO standards. Russia could follow a similar process of using the ISO standards to develop national standards. As an example, the ISO/TC 127 Technical Committee works very closely with the CEN TC 151 Technical Committee and most of the TC 151 members are also members of ISO/TC 127. The general EN Safety Standard for earthmoving machinery references over 50 of the ISO/TC 127 Safety Standards and has essentially the same requirements as the ISO standards that were already in existence when it was mandated that a safety standard should be developed. The United States also uses the ISO/TC 127 standards as the national standards. One of the objectives for ISO/TC 127 is to encourage participation in the ISO standards development process by all major economies. With such participation, input can be provided to ensure that the ISO standards are appropriate for all countries.

B. Group 2 - Setting requirements in technical regulations

1. Overview (regulatory task)

14. Identification of an optimal degree and level of detail for the requirements in technical regulations, depending on the objective of the regulations.

2. Questions

Question 1:

15. What is understood by the term "essential requirements"? What are different types of such requirements? (it would be appreciated to have examples of different scales for such requirements and indications of concrete requirements for such representative groups of products as chemical products, food products, aircraft and related equipment, surgical implants, express railway equipment).

16. It would be appreciated to have concrete examples of how essential requirements are established in different forms, for example:

- General requirements for the safety of production processes?
- Numerical index values?
- Specific parameters?
- Threshold values?

Question 2:

17. In which cases and in which form are "indirect" references to standards used (for example, harmonized standards from the list published by the European Commission)?

3. Replies from the European Commission

To question 1 (see paragraphs 15 and 16 above):

18. The notion of essential requirements should be interpreted restrictively, insofar as it was originally identified by the European Court of Justice. The non-conformance to such essential requirements is to be seen as the sole case that could justify a Member State refusing the marketing, on its territory, of a product legally manufactured and commercialized in another Member State.

19. In its Resolution of 7 May 1985, the Council of Ministers stated that essential requirements should be set out in terms of performance requirements as opposed to descriptive technical specifications so that conformance could be demonstrated more simply. A typical, simple example of an essential requirement expressed in terms of performance is the requirement to test a simple vessel to insure that it can withstand a pressure which is twice the declared working pressure of the simple vessel, regardless of how it is manufactured and with whatever material is used. The legislator decides what is the level required at any time, (it decides whether the test should be twice or three times the working pressure), whilst not getting involved in the technology issues of how to design or manufacture the products in question.

20. Essential requirements can be expressed very differently from one product sector to another, depending on the type of products or the type of risk involved. Essential requirements for the same pressure vessel mentioned above relating to its resistance to corrosion due to contact with chemicals cannot be expressed in the same manner as that for the question of resistance to pressure. It is relatively easy to set performance requirements that can be measured using measurement instruments including the levels of tolerance acceptable to the legislator for the demonstration of conformity; whereas it becomes very difficult to express the requirements in exclusively performance terms for the manufacturing and testing of machines, where the requirements have to be somewhere between identifying a performance and a descriptive technical specification. You cannot just say that a machine must stop when the worker gets too close to a moving part of the machine, because of the complexity of the machines, so a number of structural and technical elements, etc. have to be specified.

21. If one wanted to, essential requirements can also be specified in terms of performance for foodstuffs, for hygiene and pharmaceuticals. Traditionally in these areas, it is not done because the legislator is more accustomed to state in detail the characteristics of the products and because in these areas it is believed that with technological progress it is better not to 'limit' by fixed requirements for health and hygiene performance which get better every day.

22. Performance-essential requirements can be filled in by the professional standardisation community by translating the performance requirements into voluntary technical specifications. These should remain voluntary because they are the expression of the state of the art which in our technological day and age can change overnight. Hence, to go back to the example of the simple pressure vessels, the standards can set out that the manufacturer can design and manufacture a simple pressure vessel in aluminium or in steel or plastic in such a manner that when testing it to twice the pressure it does not explode.

23. If the standard were to set out how to roll cylinders, how to do the welding, etc. based on the present state of the art, maybe in 5-10 years welding technology will have changed and better solutions will have been developed. The voluntary nature of the standards allows the old techniques to carry on in the presence of the new ones, without going through the whole legislative process all over again. It is the market and the economy which will decide on the fate of old technological solutions, although legislation may continue to recognize them as being safe nevertheless.

24. Essential requirements can be set for health and safety of consumers and users (toys, personal protection equipment) for the protection of workers at the work place (machines, personal protective equipment (PPE), etc.), can be set for the protection of the environment (some elements in different directives such as machines, pleasure craft, etc.) and could be set for hygiene and health (food or pharmaceuticals or chemicals). In some areas essential requirements can be linked to the notion of compatibility of different elements, in particular where the legislation covers systems (rail transport, for example).

To question 2 (see paragraph 17 above):

25. Essential requirements should preferably be expressed in terms of performance standards, i.e. in terms of thresholds. However, these performance indicators should not be expressed as minimal requirements. They are the level required by the legislation. National authorities of the Member States are therefore not allowed to fix higher requirements in their national legislation. They can only require the level set in the essential requirement. Where a manufacturer works to higher indicators, then this relates to better quality, not better safety. In the case of a simple pressure vessel, to test to four times the working pressure, for example, does not give greater safety, but it could indicate that the pressure vessel will last longer than if tested to twice the working pressure.

26. The legislator will fix the performance levels according to policy in a given area (what is desirable in terms of public protection), to technological knowledge at the time and the state of technological development.

27. The Community system provides for “harmonized” European standards to support the essential requirements set out in legislation, i.e. standards developed on the basis of mandates given to the European standards organizations so as to ensure proper translation of those requirements into technical specifications which fulfil the regulatory requirements. In other words, there is some indirect public authority intervention which makes the link (the mandate) between the essential requirement and the harmonized standard. For legal certainty the references to the harmonized standards are published in the official journal.

4. Comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”)

To question 1 (see paragraphs 15 and 16 above):

28. As a specific example, the “essential requirements” for Earthmoving machinery are the requirements to address all safety risks for both the operator of machines and the people who work around machines. Thus, ISO standards are developed to provide technical requirements to cover all of the safety risks for each type of machine. This information is provided as performance criteria to address the risks, not as specific design criteria that would limit new ideas or the use of new technology to allow for continuous improvements in safety.

To question 2 (see paragraph 17 above):

29. The regulatory requirements for machines in the United States reference a few standards, but most risks areas are covered by the General Duty Clause, which states that “Employees shall be provided with a safe place to work”. The national standards can generally be used as the performance requirements for “a safe place to work”. For earthmoving machinery, the ISO TC 127 standards are used directly in the United States as the national standards for providing a “safe place to work”.

C. Group 3 - Conformity assessment

1. Overview (regulatory task)

30. Identification of the need for and the level of harmonization of all the forms/documents relating to conformity assessment (all the types of the certificates: documents on confirmation of the conformity assessment (CA), sanitary, veterinary, phytosanitary, fire protection and so on) when there exists a high level of intergovernmental cooperation and integration such as a customs union.

2. Questions

Question 1

31. Are there any examples of such harmonization (using the same format) of CA documents?

32. What is the feasibility of achieving the highest possible level of harmonization (advantages, usefulness)?

33. What is the level of elaboration and of acceptance (adoption) of such harmonized forms (documents)? Are they prepared by a single body on an intergovernmental level (or is it joint work)? How are they adopted: on an intergovernmental level or on the level of each contracting (participating) State?

34. How does one choose the language in which such harmonized common documents shall be prepared?

35. For which forms of conformity assessment, as well as for which regulatory/certification documents has such harmonization already been done (for example, in the EU)?

Question 2:

36. How, on a governmental level, should one regulate the physical location of certification bodies (geographical distribution) so as to be in compliance with article 5.2.6. of the WTO Agreement on Technical Barriers in Trade in order not to create extra obstacles for applicants?

37. Is the cost of services (tariffs) on mandatory conformity assessment regulated (as a common tariff) on the governmental level (for example in the EU)? In general, is the cost of mandatory conformity assessment services regulated or not?

3. Replies from the European Commission

To question 1 (see paragraphs 31-35 above):

(a) In relation to paragraphs 31-33 above

38. The draft Decision of the New Legal Framework (NLF) sets out in its Annex II a format for the EC declaration of conformity.

39. However, it cannot be excluded that various Directives add, in their scope, elements to this format, but without altering it radically.

40. Similar principles apply to technical documentation specified for the modules in NLF. Every module specifies some elements that have to be included. However, a Directive in its scope may add to these elements, while using a module.

41. The ideal situation is when all Directives using a specific module require exactly the same elements in all documents. However, this may not be the case as every Directive has its specificities.

42. The fact that every Directive chooses from the same "menu of modules" uniformizes CA methods to be used by the CA bodies, thus reducing the operational costs and the burden to the industry.

(b) In relation to paragraph 34 above

43. Conformity assessment (CA) documents may be drafted in the language of the country where the CA body is based.

(c) In relation to paragraph 35 above

44. In the NLF there is a format for an EC declaration of conformity and instructions as to what elements must be included in the technical documentation.

To question 2 (see paragraphs 36 and 37):

(a) In relation to paragraph 36 above

45. Every Member State notifies to the other Member States and the European Commission the bodies that may perform conformity assessment (CA). There are no geographical restrictions

and the relevant economic operator (manufacturer, authorized representative, etc.) may address itself to any CA body it wishes. Of course, this body must be accredited to perform CA in the area.

(b) In relation to paragraph 37 above

46. The cost for conformity assessment is not regulated

4. Comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”)

To question 1 (see paragraphs 31-35 above) and to question 2 (see paragraphs 36 and 37):

(a) In relation to paragraphs 31 to 36 above

47. From the global perspective, most countries do not require certification, so the format for certification has not been important. For countries that do not require certification, the name of the manufacturer as marked on the machine and the reputation of the manufacturer can be seen as a sort of “certification”, since the responsibility for ensuring conformance rests with the manufacturer.

(b) In relation to question 2, paragraph 37 above

48. The cost of conformity assessment is the responsibility of the manufacturer as a part of product development costs. One challenge for manufacturers is the cost of performing conformity assessment testing multiple times for different countries that require the conformity assessment testing to be done in their country.

D. Group 4 - Manufacturer’s responsibility

1. Overview (regulatory task)

49. Identification of a manufacturer/ producer's responsibility in case of damage by a product which fails to meet the mandatory requirements. The manufacturer did not use the standard which was referenced in a technical regulation (directive); the standard has a voluntary status.

2. Questions

Question 1:

50. How does the nature of a reference to a standard change the level of responsibility (depending upon “direct” or “indirect” reference)?

Question 2:

51. What are the auxiliary mechanisms ensuring the responsibility of the producer in addition to technical regulations (for example, insurance, licensing; can you provide examples to show the most appropriate schemes depending on a particular product group)?

Question 3:

52. How is the degree of a producer's responsibility measured in case a recommended harmonized standard has not been used?

3. General note and replies from EC to questions 1, 2 and 3 (see paragraphs 45-47 above)

(a) General notes

53. A concrete answer for this particular point seems extremely difficult. The "Acquis communautaires" managed by the Commission's Directorate General for Enterprise and Industry (DG ENTR) on this issue is just Directive 85/374 on product liability. The general product safety (GPS) Directive is also to be taken into account, as it requires manufacturers to place only safe products on the market. In any case, the responsibility regime covered by EC legislation is that of Directive 85/374/EEC on liability for defective products, which introduced in the Community the principle of objective liability or liability without fault. According to it, any producer of a defective product must compensate any damage caused to the physical well-being or property of individuals, independently of whether or not there is negligence on the part of the producer. Directive 99/34/EC extended the scope of strict product liability to unprocessed primary agricultural products.

54. Other responsibility regimes, such as responsibility for tort, negligence, contractual breach or special responsibility regimes have not been harmonized yet by any piece of EC legislation. They all fall under the domain of national legislation.

(b) Replies

To question 1 (see paragraph 50 above):

55. It is hard to say, as this is a particular point that has always to be assessed by a national judge. It is evident that a certification of standards can be a precious element of appraisal for the judge who must - above all - decide on the responsibility of producers for the damage caused by a defect in one of their products. The presence of a certified quality system (as a matter of fact, of any quality system) and the control guarantees it represents can, in cases of doubt, make the difference between being liable for a particular damage or not (showing the manufacturer did his best to comply with safety requirements).

To question 2 (see paragraph 51 above):

56. We might come back to this question at a later stage.

To question 3 (see paragraph 52 above):

57. This question is almost irrelevant in the light of EC legislation, as the producers are always considered responsible if any of their products has caused damage. Nevertheless, it is evident that national judges may refer to those standards in order to assess liability, and that usually they do, especially in cases where tort/negligence or contractual breach is involved.

58. Therefore, not conforming to those recommended standards is not an automatic sign of negligence: neither does conforming to it become an automatic exemption of responsibility in the case of a defective product causing damages.

59. As a final note, the producer will not be considered responsible when the defect is due to compliance of the product with mandatory regulations issued by the public authorities.

60. In general, community harmonization legislation does not fix measures which have to be taken by authorities in the case of non-compliance. This is, in principle, a matter for the Member States, who are obliged to take appropriate measures to make sure that the obligations laid down in the directives are correctly applied by manufacturers. Community law hence fixes certain obligations but it is up to the Member States how to enforce them.

61. Non-compliance with a standard is not necessarily non-compliance with the Directive. Harmonized standards are voluntary, so there is no obligation to use them. Compliance is measured to the essential requirements, not to the standard. If, however, the standard is integrated in the legislation (e.g. direct reference then it becomes obligatory and failure to apply it means that the manufacturer has not complied with the directive.

62. For measures on how to ensure better and more efficient enforcement in the EU, see new proposal on market surveillance (regulation) and traceability and other obligations on http://ec.europa.eu/enterprise/newapproach/review_en.htm

4. Comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”)

To question 1 (see paragraph 50 above):

63. Even with voluntary standards, the standards are generally considered as a requirement to minimize safety risks for products. Thus, manufacturers use the standards as the requirements for product development to provide “a safe place to work”. Voluntary standards allow the flexibility to meet the general performance criteria from standards, with new technology or through using creative solutions.

To question 2 (see paragraph 51 above):

64. In the USA the “Product Liability System”, where by manufacturers can be sued for not providing safe products, is a big incentive for manufacturers to comply with standards. To avoid

large product liability payments (millions of dollars), manufacturers selling to the USA must meet the standards, even if they are voluntary.

To question 3 (see paragraph 52 above):

65. Chair of ISO/TC 127 has not yet provided any reply to this question.

E. Group 5 -Placing products on the market

1. Overview (regulatory task)

66. There is an opinion that any product placed on a market must have a conformity declaration regardless of whether the product falls under the regulated or non-regulated sphere (in the spirit of the general EU directive on product safety). It is also implied that in the regulated sphere, apart from the conformity assessment certificate for the product the manufacturer/distributor must also provide a conformity declaration. This means that all products must have a conformity declaration (from manufacturer/distributor) and, in addition to it, some goods/products must also have a conformity certificate (if this is foreseen by a special directive).

2. Questions

Question 1:

67. Is such an approach correct? And, if so, is it a scheme of global character or are there any exceptions?

Question 2:

68. Is the registration of conformity declarations organized/carried out by organs of certification or by governmental organizations or producers (or by all of them)?

Question 3:

69. Is the existence of the conformity declaration checked (as well as that of the conformity certificate) during customs clearance?

Question 4:

70. Do directives state the validity period of a conformity declaration depending on a particular regulated group of products?

Question 5:

71. Are changes in the construction, composition or formulas of a product a basis for issuing a new conformity declaration (or a reason for terminating a previously issued conformity

declaration)? What change is considered to be important (to issue a new declaration)? Who makes a decision on whether a change is important or not?

Question 6:

72. Can it be assumed that the placing of any product on the market (under conditions when legislation obliges a manufacturer to place only safe products) without issuing a formal conformity declaration (in the form of a document established by the Government) means that the manufacturers de facto has declared that they are bearing the responsibility for the safety of a product (i.e. "tacit declaration")?

3. Replies from the European Community

To question 1 (see paragraph 67 above):

73. New Approach (NA) Directives base their conformity Assessment (CA) procedures on the modules and their variants (A, B, etc.). These modules exist in the old (from 1993) and in Annex I of the New Legal Frameworks (NLF). Every NA Directive, depending on the nature of the products it deals with, may choose from this menu of modules. Every non NA Directive has its own procedures.

To question 2 (see paragraph 68 above):

74. The manufacturer declares the conformity of its products. Depending on the CA module, there may or may not be a need for a CA notified (accredited) body to carry out tests, examine the product/production procedure, etc. and issue a certificate of conformity in respect of the tests and examinations that the CA body carried out.

To question 3 (see paragraph 69 above):

75. Customs require that all documentation set out in the relevant Community legislation be submitted to them.

To questions 4 and 5 (see paragraphs 70 and 71 above):

76. A manufacturer must keep its declaration of conformity at the disposal of public authorities for 10 years; however, this period may be altered by the relevant legislative act. Changes to the product need a new conformity assessment, according to the dispositions of each CA module.

To question 6 (see paragraph 72 above):

77. Conformity assessment is always necessary before placing a product on the market.

4. Comments from the Chair of ISO/TC 127 ("Earthmoving Machinery")

To question 1 (see paragraph 67 above):

78. In most countries, a manufacturer's declaration of conformity is required and not a formal conformity declaration for a product. However, conformance may also be declared in the Operations Manual that is provided with a product or as a label on the product. As an example, for earthmoving machinery, the engine has a label stating compliance for emission regulations and the structures for protecting operators have a label showing compliance with ISO standards for operator protective structures. For large manufacturers, their name on the product can be seen as a sort of conformity declaration, since, in addition to the company's legal responsibility, their reputation and future success depends upon conformance with all legal and safety requirements.

To question 2 (see paragraph 68 above):

79. For countries that do not require a conformity declaration, manufacturers do their own conformity assessment testing. Some manufacturers may use third party groups for all or part of the conformity assessment testing. In both cases, the manufacturer is responsible for the conformity assessment.

To question 3 (see paragraph 69 above):

80. Manufacturers monitor new standards and regulations and regularly update products to comply with the new requirements. A reasonable time period is needed to respond to changes in standards and regulations. For complex products, like earthmoving machinery, two to four years may be required to develop and test the changes required to comply with new requirements.

To question 4 (see paragraph 70 above):

81. With a manufacturer's declaration of conformity, the manufacturer assumes the responsibility for conformity assessment testing and declaration of conformity. Complying with the standards and regulations requirements is necessary to meet customer demands and to continue selling the product.

To question 5 and 6 (see paragraphs 71 and 72 above):

82. The Chair of ISO/TC127 has not yet provided any reply to these questions.

F. Group 6 - Regional technical regulations

1. Overview (regulatory task)

83. The possibility of adopting unique (harmonized) technical regulations for a regional integration grouping of States (Commonwealth of Independent States (CIS), Eurasian Economic Community (EurAsEC)) should be ensured.

2. Questions

Question 1

84. Can a technical regulation be adopted as an international agreement (are there legal or organizational obstacles)?

Question 2

85. The possibility exists for a legal/organizational conflict with the national legislation of a country, which is a member (at the same time) of several regional groupings of States and when under different groupings technical regulations on the same types of products are developed in parallel and adopted (i.e. the work done in CIS and EurAsEC)? Under an assumption of the existence of two parallel technical regulations (TRs) for the same product, does it mean that a stricter version of TR for a particular product will be applicable for a country and for its imports (and the “softer” TR will be used only for exports to countries which opted for such a TR)?

3. Replies from the European Commission

86. The European Commission has not yet provided any replies.

4. Comments from the Chair of ISO/TC 127 (“Earthmoving Machinery”)

To question 1 (see paragraph 84 above):

87. Coordinating regulations is a challenge because the political systems are different in every country. However, if the technical requirements for regulations are based on ISO standards, then the global regulations can have the same technical requirements. The (UNECE WP.6) sectoral initiative on “Earthmoving Machinery” (based on UNECE recommendation “L” see http://www.unece.org/trade/ctied/wp6/documents/wp6_02/wp6-02-07e.pdf) outlines the general requirements for regulations that will lead to global harmonization of the regulations. For products that are low volume, complex to develop, and have similar applications in all countries, such as earthmoving machinery, global regulations are important for manufacturers. At the last Exposition for Earthmoving machinery in Germany, manufacturers from Russia, China, India, Japan, the United States, and many European countries showed machines that they would like to sell globally. The coordination of global regulations would help these manufacturers, including those from Russia, who want to sell machines globally.

To question 2 (see paragraph 85 above):

88. Conflict of technical requirements can be minimized if the technical regulations have general requirements, such as in the EU Machine Safety Directive, and the technical

requirements are based on ISO standards. The ISO standards should have clear descriptions of the products covered by the standards.

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