Final report on alignment of the R&TTE Directive with the Decision 768/2008/EC

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1 Executive Summary

1.1 Introduction

TCAM 28 of 7th December 2009 decided to create an ad-hoc working group to define options for the revision of the R&TTE Directive and assess their impact regarding the alignment of the Directive to the New Legislative Framework (NLF\(^1\)), with the exclusion of traceability and compliance issues which are handled by a separate working group. The background of this task is mentioned in document TCAM: (28)29 Options Obj. 20 of alignment to NLF, Proposed options for Objective 20 alignment to NLF.

In accordance with the terms of reference, the objective of the ad-hoc working group NLF is to assist the Commission in the preparation of the revision of the R&TTE Directive, regarding the following objective:

- To align the R&TTE Directive with the provisions of the New Legislative Framework in order to achieve the intended goals of the NLF. The ad-hoc working group shall not deal with traceability and compliance issues, which are to be dealt with by another working group.

The NLF intends to facilitate the functioning of the internal market for goods, to strengthen and modernise the conditions for placing products on the EU market and to introduce common principles to be applied across sectoral legislation in areas such as:

- market surveillance, including imports
- accreditation
- harmonised definitions facilitating improved coherence of legal texts
- obligations for economic operators
- conformity assessment procedures
- EU safeguard measures

The NLF consists of three documents, from which two are relevant for the R&TTE Directive, the EC Regulation 765/2008 and EC Decision 768/2008. The Regulation 765/2008 is since 1st January 2010 directly applicable for all Member States. The Decision 768/2008 is a general document establishing a framework for the marketing of products. This decision provides reference provisions in its Annexes I, II and III that are to be used when drafting sectoral legislation such as the R&TTE Directive.

The objectives of the ad-hoc working group were to:

- identify those NLF issues that should be included in the R&TTE Directive;
- identify options for achieving an alignment considering the needs and possible specificities of the R&TTE area;
- assess the impact on the objective to be attained as well as other ensuing costs and benefits as stated in the Commission’s Impact Assessment Guidelines (IAG)

The deliverable of the ad-hoc working group is a report providing the options and their assessment. A first progress report has been provided to the Commission by the TCAM meeting which took place on the 9th of March 2010 in Luxembourg. The final report was expected to be available by 15th of May 2010, however on the request of the chairman this date was extended with three weeks.

The working group was chaired by the Chairman of ADCO R&TTE (Mr. Bert van Dijk (NL) who has organised the work of the group. This working group was open to all concerned stakeholders (e.g. Member States, market surveillance authorities, industry, Notified Bodies). The working group liaised with the TCAM ad-hoc working group on traceability and compliance.

\(^1\) Revision of the New Approach on the free circulation of products as defined by Decision 768/2008/EC
1.2 Process of activities

The ad-hoc working group started its work by the beginning of 2010. Participants of the ad-hoc working group were representatives of the European Commission, ADCO R&TTE, R&TTE CA, ECO, ETSI and industry. The activities of the working group were monitored by the circa 80 representatives of organisations, registered in the CIRCA server.

The ad-hoc working group agreed that the principles of the NLF were fully accepted and that the activities of working group should be limited to the activities described in the terms of reference, agreed by the TCAM.

During the five meetings of the ad-hoc working group, all provisions and articles of the Decision 768/2008/EC were analysed and discussed, by keeping in mind the inclusion of the selected articles of the Decision 768/2008/EC in the new R&TTE Directive which should result to:

- clarify and simplify the provisions of the new R&TTE Directive;
- improve the level of compliance with the essential requirements;
- reduce costs and administrative burden;
- provide a suitable environment for the introduction of innovative products;
- revise the safeguard procedure and strengthen the market surveillance;
- improve the cooperation, coordination and exchange of information between Market Surveillance Authorities.

1.3 Recommendations

For each provision or article the ad-hoc working group has provided a relevant recommendation on whether or not to include the provision or article in the new R&TTE Directive, whether to modify the provision or article in order to take into account specificities of R&TTE area, or to not include it. The group has produced 53 recommendations in total.

The ad-hoc working group recommends the European Commission that articles R7, R8, R11, R13, R14, R15, R16, R18, R19, R20, R22, R23, R24, R25, R29 and R30 of the Decision 768/2008 may be included without changes in the new R&TTE Directive.

The remaining provisions or articles were also considered in detail. Modifications needed to be included in the new R&TTE Directive or in the new R&TTE Guide or new Blue Guide were also included in the Recommendations. It was agreed by the ad-hoc working group that the formal wording of these recommendations in the new R&TTE Directive might have to be adapted to the specific wording of the new R&TTE Directive or in the Blue guide or R&TTE guide.

Chapters 3, 4, 5 and 6 of this report contain detailed information on the considerations and the resultant recommendations of the ad-hoc working group. Finally, the complete overview of the 53 recommendations and the relevant articles, are given in chapter 7.
2 Impact assessment procedure

The ad-hoc working group agreed that the principles of the NLF were fully accepted and that its activities would be limited to the activities described in the terms of reference. During the meetings all provisions of the Decision 768/2008/EC were analysed and discussed, keeping in mind inclusion of the selected provisions of the Decision 768/2008/EC in the revised R&TTE Directive should, results to:

1. clarify and simplify the provisions of the new R&TTE Directive;
2. improve the level of compliance with the essential requirements;
3. reduce costs and administrative burden;
4. provide a suitable environment for the introduction of innovative products;
5. revise the safeguard procedure and strengthen the market surveillance;
6. improve the cooperation, coordination and exchange of information between Market Surveillance Authorities.

2.1 Clarify and simplify the provisions of the new R&TTE Directive

In the Commission’s progress report it is indicated that the R&TTE Directive has to be improved in order to make it clear and simple. Businesses and industries, but also national authorities that are responsible for the implementation and enforcement of the Directive, benefit from clear and simple rules. Clear and simple rules will improve the implementation and enforceability of the Directive and should reduce also the administrative burden. The introduction of the provisions of the New Legal Framework should therefore result in clear and simple rules. It should not make the R&TTE Directive more complex or more difficult to understand.

2.2 Improve the level of compliance with the essential requirements

The ultimate goal of the Directive is to ensure that only products compliant with the provisions of the R&TTE Directive and in particular the essential requirements are brought to the market. There are two issues crucial in this matter. First, how is a product judged compliant, and second, what happens if a product is found not-compliant.

The first question touches the conformity assessment procedures. Apart from the full quality assurance option, the current R&TTE Directive has basically two routes for conformity assessment: (a) self declaration by the manufacturer without a mandatory involvement of a third party in cases where harmonised standards are used in full and (b) self declaration by the manufacturer with a mandatory involvement of a notified body when a harmonised standard hasn’t been applied or only partly. It was obviously considered that one could trust manufacturers to know how to apply a harmonised standard, but when no such harmonised standard was applied it was important to have a third party with specific knowledge to assess if the essential requirements were complied with. This proves that conformity assessment procedures should be specified to the effect whether they improve compliance with essential requirements.

The second issue regards the market surveillance. As the R&TTE Directive has replaced type approval by self declaration from the manufacturer, national authorities have to ensure that equipment on the market comply with the provisions of the Directive (while the responsibility for placing on the market compliant equipment lies with the economic operators). Market surveillance authorities should have the provisions to firstly be able to remove non compliant products of their national market and secondly to launch safeguard clauses at Community level for severe non compliances. In this manner safeguard clauses can have a positive influence on compliance with the essential requirements

2.3 Reduce costs and administrative burden

The inclusion of provisions of the New Legislative Framework in the R&TTE Directive should preferably not lead to additional costs and burden for economic operators and national authorities. However the NLF
itself sets some additional requirements. In the field of the NLF alignment, the reducing of administrative costs and burden may be achieved by avoiding discrepancies between directives applicable to same products as radio controlled toys which are covered by both Toys and R&TTE Directives.

2.4 Provide a suitable environment for the introduction of innovative products

The new R&TTE Directive should continue to create a suitable environment for the introduction of innovative products. Especially the ongoing and anticipated technological developments make it necessary that the R&TTE Directive is transformed into a “future proof” framework that facilitates the marketing of (innovative) telecommunications equipment. It is to be noted that the R&TTE Directive is not the only framework, which ensures that innovative equipment can be put on the market. Spectrum regulation (including least restrictive conditions such as EC decision at 2.6 GHz (EC/2008/477) and regular review of EC Decision (i.e. EC Decision on SRD updated on an annual basis) ensure that innovative equipment can be put on the market and used. In the meantime an ad-hoc working group on innovation has been formed to discuss this issue in depth.

2.5 Revise the safeguard procedure and strengthen the market surveillance

The Commission and Member States are of the opinion that the current safeguard procedure is over bureaucratic and time consuming and therefore ineffective (mentioned in the progress report of the European Commission). The safeguard procedure (Article 9) should be modified in such a way that it is only applied in justified cases. Market surveillance should also ensure that there is a level playing field for all stakeholders by taking action against products and economic operators that are not fulfilling the requirements of the directive.

2.6 Improve cooperation, coordination and exchange of information between market surveillance authorities

The cooperation, coordination and information exchange between the national market surveillance authorities should be further improved.

Impact assessment procedures are based on the following essential goals:
- clarify and simply the provisions of the new R&TTE Directive;
- improve the level of compliance with the essential requirements;
- reduce costs and administrative burden;
- provide a suitable environment for the introduction of innovative products;
- revise the safeguard procedure and strengthen market surveillance;
- improve cooperation, coordination and exchange of information between market surveillance authorities.

Figure 1 impact assessment procedures

This type of impact assessment procedures were used for advising the European Commission on the inclusion of the provisions of Decision 768/2008/EC in the new R&TTE Directive.
3 Ad-hoc working group analysis of the provisions of Decision 768/2008/EC

Accepted provisions of the Decision 768/2008/EC by the ad-hoc working group alignment

It is agreed that following provisions R7, R8, R11, R13, R14, R15, R16, R18, R19, R20, R22, R23, R24, R25, R29 and R30 may be included in the new R&TTE Directive. (Recommendation 1)

For the remaining articles, in-depth discussions were held. Below mentioned articles were considered needing modifications in order to be included in the new R&TTE Directive and suggestions for their implementation.

3.1 Article R1: Definitions

1) Generally, all provisions on definitions as laid down in Article R1 can be included in the new R&TTE Directive. However, they have to be amended according to the wording of the R&TTE Directive (e.g. the word “product” in the NLF provision would have to be changed to “product” etc.) as it has been done e.g. for the new Toys Directive where the word “product” has been changed to “toy”. (Recommendation 2)

Some members of the ad-hoc working group expressed doubts whether this replacement is really necessary. It may depend on the definition of “product” which could refer to telecommunications terminal equipment and radio equipment.

2) The ad-hoc working group is of the opinion that the Commission should consider if an alignment to “product” in all directives is needed/wanted (Recommendation 3).

3) Clarification from the Commission is needed on the definition of “risk” and its link with the essential requirements of the R&TTE Directive. However this issue is not under the responsibility of this ad-hoc working group (Recommendation 4).

4) It should be clarified what is meant by conformity assessment body and notified body. Both terms are used in the NLF. The following definitions may be considered to be inserted in the ne R&TTE Directive:
   - ‘Conformity assessment body’ means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
   - ‘Notified body means a conformity assessment body that is notified according the provisions of this Directive’

The ad-hoc working group therefore recommends to add or to merge both definitions in the new R&TTE Directive (Recommendation 5).

5) The NLF mentions about “CE Marking” (e.g. art. R11) and “Conformity marking” (e.g. point 4 of Module A). Therefore it is proposed by the ad-hoc working group to add a new definition in the new R&TTE Directive on the term “Conformity marking” and specify that it includes CE marking and all other marks required by the new R&TTE Directive. This would clarify the inclusion of the identification number of the involved notified body and any additional mark set out in the new R&TTE Directive.

A possible definition may be: “conformity marking means the CE marking followed by, if applicable, the identification number of the involved notified body and, if applicable, the class identifier [plus any potential CE related marking required by the new R&TTE Directive]” (Recommendation 6).

6) State of the art

The new conformity assessment modules should require that the product shall reflect the state of the art when placed on the market. This state of the art is reflected in the applicable harmonised standard. This means that if there is a change in the applicable harmonised standard, the manufacturer shall assess the consequence on his product and when applicable, he should assess again the compliance before the withdrawal of the previous harmonised standard. This would avoid the actual problem with the application of Annex IV where some manufacturers mean that this assessment is valid for ever.
The manufacturer has to ensure that new batches of his product comply with the essential requirement.

The definition on the “state of the art” in the new Directive R&TTE should be clarified by e.g. inserting a ‘whereas’ based on whereas 13 of the EMC Directive 2004/108/EC and completed: “Harmonised standards reflect the generally acknowledged state of the art as regards electromagnetic compatibility matters in the European Union. It is thus in the interest of the functioning of the internal market to have standards for the electromagnetic compatibility of equipment which have been harmonised at Community level. Once the reference to such a standard has been published in the Official Journal of the European Union, compliance with it should raise a presumption of conformity with the relevant essential requirements, although other means of demonstrating such conformity should be permitted. Compliance with a harmonised standard means conformity with its provisions and demonstration thereof by the methods the harmonised standard describes or refers to.” (Recommendation 7)

### 3.2 Article R2 Obligations of manufacturers

1) R2.3, Technical documentation: The ad-hoc working group agreed that the specified period, to make the technical documentation and the EC Declaration of Conformity available, should be a period of ten years (Recommendation 8).

2) R2.4 states “Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall adequately be taken into account”. This should also be the case when a manufacturer has chosen to not to declare conformity to harmonised standard (e.g. conformity declared to proprietary specifications) and the state of the art described in the applicable harmonised standard has changed even if the technical specifications used for declaring the conformity haven’t changed.

The Commission was requested to clarify if the wording of the first paragraph of article R2.4 is also applicable if the manufacturer hasn’t fully used a harmonised standard to declare the conformity. Clarification should be given either in the Directive or in the revised Blue Guide.

In response to this request, the Commission’s view is that R2.4 is related to the obligation of the manufacturer to continuously update the Declaration of Conformity. When the legal requirements of the New Approach Directives do not change in time (unless there is legal revision) the way to comply with them does in practice evolve with the state of the art. Harmonised standards in general are the reference to assess an evolution in ‘state of the art’.

Therefore:
- equipment, marketed by manufacturers who choose to base the conformity assessment on harmonised standards, must comply with the published version of the applicable harmonised standards at the moment of placing the equipment on the market;
- Equally, those manufacturers who choose to not or partly apply harmonised standards for the conformity assessment must take into account the state of the art (in general as reflected in the harmonised standards) at the moment of placing the equipment on the market.

The ad-hoc working group recommends adding this clarification in the new blue guide or the new R&TTE guide. (Recommendation 9)
3) R 2.4, second paragraph: “When deemed appropriate with regard to the risks […] if necessary, keep a register of complaints, of non-conforming products and products recalls etc.” Clarification by the Commission is needed regarding the following points:

- Which kind of register is needed?
- when it is deemed necessary to keep one?

The Commission’s view is that this article follows the wording of the GPSD Directive and that the expression “when deemed appropriate” refers to the manufacturer. It is for the manufacturer to assess when to carry out sample testing, investigate and if necessary keep a register. As for the form of the register, it has been explicitly left open in order to grant manufacturers the freedom of deciding how to keep it, as long as the information mentioned in the Article: complaints, non-conforming products and products recalled, is available. The ad-hoc working group recommends to keep the wording of R2.4 second paragraph and to add this commission view in the new blue guide (Recommendation 10).

4) R2.6: Clarification by the Commission was needed with regard to the words “where that is not possible”. The Commission considers this article as self-explanatory. It imposes on the manufacturer the obligation to provide his contact details with the product, either on the product itself, or in the documentation accompanying the product.

The ad-hoc working group noticed that the size restriction in R2.5 and R2.6 were intended to have the same meaning. Therefore, since the wording of R2.5 is clearer ("where the size or nature of the product does not allow it…"), it is suggested to also use this text for R2.6. (Recommendation 11)

This suggestion would be in line with whereas 25 of Decision 768/2008/CE: “When placing a product on the market, every importer should indicate on the product his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.”

5) Article R2.7: The ad-hoc working group discussed whether article 6.3 of the current R&TTE Directive:

- should be incorporated in the new text, when R2.7 is inserted; or
- an additional section is needed to specify what shall be part of the user instructions.

This issue was not further discussed as this is not a real “alignment” problem. This should however be kept in mind when dealing with the revision of the R&TTE Directive. It would make sense to have all obligations for the manufacturer under the same chapter.

Furthermore, the ad-hoc working group discussed the requirement “…shall ensure that the product is accompanied by instructions and safety information…” and concluded that clarification on the term “instructions” in the context of the R&TTE Directive is needed. Current Directive considers under Article 6.3 obligations regarding “intended use of equipment”, “safety instructions”, “geographical information”, etc… to be included in the information for the user. However, it does not consider any requirement on the manual itself.

Therefore, the ad-hoc working group recommends considering this issue when implementing Article R2.7. For the particular case of the R&TTE Directive, a better wording would be “…and is accompanied by the Declaration of Conformity and required information for users in the instruction manual ….”

Taking the above into account the ad-hoc working group favours having the obligations of Article 6.3 of current R&TTE Directive incorporated into article R2.7 it has to be mentioned that “required information for users” includes all requirements from article 6.3 of the current R&TTE Directive (Recommendation 12).
6) Article R2.8: This article requests manufacturers, in cases of products which represent a risk, to “immediately inform the competent national authority in the Member State…”

The ad-hoc group considered relevant to suggest the Commission to provide all economic operators with a mechanism that allows immediate notification at one single point in cases where the product was placed on multiple Member States’ markets. The “Business Application” operated under the GPSD can serve as example for a solution. This would apply also to responsibilities of other market players (Recommendation 13).

3.3 Article R3 Obligations of authorised representatives

Article R3.2 (a): As mentioned in Recommendation 5, the ad-hoc working group agreed that the period to make the EC-declaration of conformity and the technical documentation available should be kept as in current Directive. Therefore, the wording in this section is suggested to be aligned accordingly to article R2.3 and should read: “… for 10 years after the product has been placed on the market” (Recommendation 14).

3.4 Article R4 Obligations of importers

1) Article R4.2: The wording “…and is accompanied by the required documents,…” might be misleading as pointed out in Recommendation 6. It is therefore proposed to modify this requirement in order to be more specific. For the particular case of the R&TTE Directive, a better wording would be “…and is accompanied by the Declaration of Conformity and required information for the users,…” (See also Recommendation 12).

2) Article R4.3: It is unclear in which situation it is allowed to put the name of the importer only on the packaging or in a document accompanying the product instead of on the product itself. Therefore it was suggested to combine the clarification given in “whereas 25” with the text of Article R4.3 (i.e. adding the following sentence to R4.3: “This includes cases where the size does not allow it or the importer would have to open the packaging to put his name and address on the product”) (Recommendation 15).

3) Regarding the requirement for the importer to add his contact details (i.e. the traceability information) on the product or packaging or user documentation, the ad-hoc working group found necessary to clarify the cases where a manufacturer or his authorised representative is already established in the EU. In those cases, it was proposed by Industry that importers would not need to add his contact details since the responsible in the EU (i.e. manufacturer or his authorised representative) is already specified. Also see ERP Directive 2009/125/EC, article 4. Some MSA consider that there could be a distinction for cases where the manufacturer and importer are the same entity or if there is an unique importer.

For this reason, the ad-hoc working group recommends that this issue should be clarified in the Blue Guide noting that this has already been done for the guide of the Toy Directive (Recommendation 16).

3.5 Article R5 Obligations of distributors

1) Article R5.2: The wording “…that it is accompanied by the required documents and by instructions and…” might be confusing and it is proposed to modify this requirement in order to be more specific. The same concern has already been addressed in (See also Recommendation 12).

2) Article R5.5: The distributor should cooperate with the MSA and provide it with “all information and documentation necessary”, to make it possible to assess whether a product fulfils the essential requirements.
The Commission is of the opinion that it is reasonable to assume that "all the information and documentation necessary to demonstrate the conformity of a product" includes the technical documentation. However, this does not imply that distributors need to have the technical documentation available themselves. If they are confronted with such a request, they should be able to provide it on request within a reasonable timeframe.

Some MSA are of the opinion that article R5.5 and the interpretation form the Commission are clear enough and distributors should be able to provide the relevant documentation, including the technical documentation, upon request from authorities.

Some other MSA and Digital Europe have reservations about the interpretation from the Commission, since it makes a tremendous difference asking directly a distributor for the Technical Documentation instead of obtaining it through the distributor. For this reason, they are the opinion that if distributors are confronted with such a request from a market surveillance authority, then distributors shall cooperate with that authority in order to put him in contact with the responsible person for placing the product on the market and obtain the technical documentation.

The ad-hoc working group is of the opinion that a period of maximum of three weeks should be seen as a reasonable timeframe in order to obtain the documentation necessary to demonstrate the conformity of a product through distributors. This recommendation should be reflected in the R&TTE Guide (Recommendation 17).

3.6 Article R6: Cases in which obligations of manufacturers apply to importers and distributors

The ad-hoc group considered that a clarification from the Commission is needed on whether the details of the original manufacturer have to be provided in case where an importer or distributor is considered to be a manufacturer.

The Commission’s view is that in cases in which obligations of manufacturers apply to importers and distributors or to specify conditions under which an importer may overtake the responsibilities of a manufacturer. It seems logical to assume that if an importer or distributor shall be considered the manufacturer of a product, the details of the original manufacturer do not longer need to be on the product. The ad-hoc working group agreed with the clarification from the Commission and considers that it should be part of a new version of the R&TTE Directive Guide or Blue Guide. (Recommendation 18)

3.7 Article R9: Formal objection to a harmonised standard

1) The only difference Decision 768/2008 introduces is that the 98/34-EC Committee has to consult the relevant European standardization body. (R9.1 "The Committee shall, having consulted the relevant European standardization bodies, deliver its opinion without delay."). Before the Commission gives mandates for harmonised standards to the European standardization bodies, the 98/34-Committee has to be consulted according to art. 6.4. of the Directive 98/34/EC.

The ad-hoc working group is of the opinion that TCAM should be able to take binding decisions on the conditions under which a harmonised standard raises presumption of conformity (i.e. take binding decisions on the revision of a harmonised standard). If that is not possible then an equivalent disposition to current article R&TTE 5.3 should be added to the NLF R9. In the current directive the Commission may after consulting TCAM publish guidelines on the interpretation of harmonised standards or the conditions under which compliance with the standard raises a presumption of conformity and may also withdraw harmonised standards by publication of a notice in the OJEU. This provision (article 5.3) should be included in the new Directive. When doing this the commission needs only to consult TCAM and not the Committee set up by article 5 of Directive 98/34. Following the NLF, an extra degree of bureaucracy will be added where this Committee is consulted even though it has no expertise on radio matters (Recommendation 19).
2) The ad-hoc working group considers that TCAM is the competent body for addressing shortcomings of harmonised standards. In the current R&TTE Directive TCAM is the only body involved in article 5 of the R&TTE Directive (harmonised standards). To keep the reactivity of the process it would be preferable to have only TCAM involved when dealing with such shortcomings.

The proposal is to have only TCAM involved as is the case in the current R&TTE Directive. (Recommendation 20)

3.8 Article R10: EC declaration of conformity (DoC)

The ad-hoc working group considered that this article needs to be adapted in order to cover current R&TTE Directive situation regarding EC declaration of conformity. Chapter 6 of this report reflects the observations and justifications that the ad-hoc working group considers need to be performed over article R10 and Annex III of 768/2008/EC. (Recommendations 21)

3.9 Article R12: Rules and condition for affixing the CE marking

1) Article R12.1: The ad-hoc working group agreed that it is advisable to have a general interpretation on the meaning of “data plate” in the new “Blue Guide”. This is related to the difficulties faced by MSAs when performing surveillance activities to find the required marking on the product. (Recommendation 22)

2) The ad-hoc working group also considered necessary a clarification by the Commission about which marks should be part of the conformity marking (see 3.1 and recommendation). The question arose if the CE-marking does include the notified body (NB) identification number and, if applicable, the alert sign.

In response to this question, the Commission is of the opinion that the CE marking under the NLF only means the actual CE mark, according to Article12.2 and 12.3 of the Decision 768/2008/EC: “the CE marking shall be followed by a pictogram or any other mark [...] or by the identification number of the notified body”. The ad-hoc working group accepted the reply from the Commission. The group is however of the opinion that in this case, rules on the aspect of this additional marking should be precisely defined (e.g.” It must have the same height as the CE marking.”) Furthermore, the position of the additional marking should also be defined (e.g. “It must directly follow the CE marking”). (Recommendation 23)

3) Article R12.3: this paragraph mentions that the CE marking shall be followed by the identification number of the notified body, where that body is involved “in the production control phase”. There was some confusion about the meaning of the words “involved in the production control phase”.

Belgium pointed out that the involvement of NB in the conformity assessment depends on the modules that will be incorporated into the new R&TTE Directive. In some modules the NB is involved in production control. In module B “design type”, the NB is only involved in evaluating the technical file. The NB is in that specific case not involved during production even if module B “type design” is followed by module C. As a consequence there is no need to include a NB number in the CE marking for that kind of conformity assessment procedure.

The ad-hoc working group consequently agreed that it should be made clear that the NB identification number has to be put with the CE marking only in cases where a notified body is involved in the conformity assessment reflected in Annex H (Recommendation 24)
Second paragraph suggests that the Notified Body identification shall be affixed by the body itself or under his instructions by the manufacturer or authorised representative. The ad-hoc working group considers that the way the Notified Body identification should be affixed is already described before. Therefore, it is proposed to delete this paragraph. (Recommendation 25)

3.10 Article R17 Requirements relating to notified bodies

1) The ad-hoc working group agreed that the tasks of a Notified Body under the R&TTE Directive should be specified. This should be done in relation to the technical abilities of the Notified Body and taking into account the relevant conformity assessment modules put in place.

The ad-hoc working group’s view is that this should be part of Article R17.6 which should be rewritten. A Notified Body can be designated for one or more conformity assessment procedures (modules). The designation should state for which modules (and eventually for which products) a Notified Body is designated. (Recommendation 26)

2) Article R17.10: There was some discussion on this paragraph. It was questioned if a Notified Body should be obliged to cooperate with “all” competent authorities (MSAs) of all Member States and not only with the competent authority of the designating Member State.

Belgium’s view is that the ad-hoc working group should take a look at Article 41 “instructions to the notified body” of the new Toys Directive (Directive 2009/48/EC). This Article specifies” that MSA may request a Notified Body to provide information relating to any EC-type examination certificate.

It follows from this Article that the Notified Body is obliged to cooperate with any MSA and not just with the MSA of the designated Member State. This even is an obligation for all Notified Bodies and not only for the European Notified Bodies! This should also be taken into account when re-discussing the Mutual Recognition Agreements (MRAs) (Recommendation 27)

3) Second part of article R17.4 and second part of article R17.6 should be amended to take care of the role of a Notified body working in the field of the R&TTE Directive. An R&TTE Notified Body shall be a third-party body independent of the organisation or the product it assesses and not involved in testing equipment. Therefore there is also no need for test equipment (Recommendation 28)

4) Article R17.10 should be amended to avoid inconsistency with the provisions of e.g. Annex III which foresees that a national market surveillance authority may request information to a file processed by a notified body, even if this notified body is not located in the jurisdiction of the national market surveillance authority which is requiring the information. Therefore the proposal is to start this paragraph with the wording “without prejudice to the obligations of the notified body described in the according conformity assessment modules …’ (Recommendation 29)

5) To take the specificity of the radio equipment, especially by radio products from a new technology, the ad-hoc working group expressed the view that involved Notified bodies should be aware about the development of radio technologies and therefore participate or to be aware of the work in the relevant European frequency planning bodies (CEPT) and Community committees (RSCOM, RSPG, …). This should be included in a new article R17.12 in the new R&TTE Directive. (Recommendation 30)

6) The ad-hoc working group also proposes to amend article R17, dealing with the requirements relating to Notified Bodies as below stated (other paragraphs of article R17 remain unchanged) (Recommendation 31):

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, testing, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the
parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

6. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities. (note: it is suggested to delete this part of the sentence)

10. Without prejudice to the obligations of the notified body described in the according conformity assessment modules, the personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under … [reference to the relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

12. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant European frequency planning bodies and Community committees established under the relevant Community legislation and apply as general guidance the decisions, studies and documents produced as a result of the work of those groups.

3.11 Article R21: Accredited in-house bodies
This Article should not be included in the new R&TTE Directive. The R&TTE Directive does not allow the use of accredited in-house bodies to carry out conformity assessment activities as a notified body for the undertaking of which it forms a part for the purpose of implementing the procedures set out in this Directive. (Recommendation 32)

3.12 Article R26 Challenge of the competence of Notified Bodies
The ad-hoc working group agreed to include this article in the new R&TTE Directive, and notes that attention has to be paid to the consequences for the MRAs. It is therefore recommended to take this into account when updating the relevant MRAs regarding the new R&TTE Directive. (Recommendation 33)

3.13 Article R27 Operational obligations of notified bodies
This provision should be included in the new R&TTE Directive. With regards article R27.2: Several parts of this Article need to be clarified. This especially applies to the second sentence (taking into account the size of an undertaking etc.). The meeting is of the opinion that this can be done in a revised Blue Guide (Recommendation 34).

3.14 Article R28 Information obligation on notified bodies
Article R28 gives information on obligations for the notified bodies only against the notifying authority, even if in the various conformity assessment modules, there is also an obligation to inform Commission and Market surveillance authorities.

Therefore, the ad-hoc working group recommends adding in article R28 (Information obligation on notified bodies) the text “Notified bodies shall fulfil other information obligation laid down in Annex III and IV” in order to cover other information obligation laid down in the conformity assessment procedures (Annex III and IV) (Recommendation 35)
3.15 Article R31 Procedures for dealing with products presenting a risk at national level

1) Article R31.1: The ad-hoc working group agreed that an explicit reference should be added to the essential requirements of the R&TTE Directive. Moreover the words “present a risk to the health or safety of persons or to other aspects of public interest protection covered by this [act]” should read “present a risk to the essential requirements of this (R&TTE) Directive as laid down in Article….”. The ad-hoc working group is of the opinion that the current text of Article 9.5 of the R&TTE Directive may be copied into the new R&TTE Directive in order to solve this issue. (Recommendation 36)

2) Using a harmonised standard for conformity assessment gives presumption of conformity. When at least one of the declared harmonised standards has not been correctly applied then there is no more presumption of conformity. Therefore, incorrect application of a harmonised standard must be recognised as a basis for safeguard action (i.e. falling under the article R31).

   The Commission’s view is, that in that case a safeguard measure under article 9.2 (a) of the current R&TTE Directive (i.e. incorrect application of the harmonised standard) can be issued, article R31 as drafted in the Decision 768/2008/EC does not provide for a procedure like the one established in Article 9.2(a) of the current R&TTE Directive.

   According to the above analysis, the ad-hoc working group proposed that Article 9.2a of the present R&TTE Directive has to be incorporated, as incorrect application of a harmonised standard must be recognised as a basis for safeguard action. Therefore it was agreed to propose adding to R31.5 the same wording as in article 9.2(a) of the current Directive: (c) incorrect application of the harmonised standard (Recommendation 37)

3) The MSA are of the opinion that Article R31.8 should be replaced as follows: "Member states shall take the measures necessary to ensure that the non-compliant product is withdrawn from their market and shall inform the Commission accordingly, without delay". (Recommendation 38)

   This recommendation is drawn from article R32.2 which deals with the case where a safeguard measure is considered justified after an objection was raised. R31.9 and R32.2 have the same premises: that a safeguard measure is considered justified. Therefore it is logical to align both consequences and it is appropriate that the corresponding equipment be withdrawn from the market as prescribed in R32.2. The consequence of such a change would be to strengthen safeguard measures that are deemed justified.

3.16 Article R32 Community safeguards procedure

   Article R32.3: the ad-hoc working group is the opinion that this provision on shortcomings in the harmonised standards should be aligned with article R9, the matter should be brought before TCAM (instead of the Committee set up by article 5 of the 98/34). (Recommendation 39)

3.17 Article R33 Compliant products which present a risk to health and safety

1) The ad-hoc working group questioned the origin and reason of this Article in the Decision 768/2008/EC. Since risks for health and safety are already addressed as essential requirements in the R&TTE Directive, this article might be seen as redundant. It was therefore unclear if this Article should be included in the new R&TTE Directive.

   The Commission answered to this question saying that they are preparing guidelines for the safeguard procedure. However, in the meantime it is possible to say that Article R33 has been designed to be used in very exceptional circumstances, as in most of the cases, compliant products should not present a risk to health and safety. Possible cases could be cumulative effects or innovative products with characteristics not covered by the essential requirements.
• France proposes to limit the title to “Compliant products which present a risk” and add art 9.5 of the present R&TTE Directive to the new R&TTE Directive;
• Belgium pointed out that R33 is not included in the new Toys Directive and was not sure of the underlying arguments.
• Industry and NL agree that accumulative effects should be covered by this Article R33. However, the wording “…it presents a risk to the health or safety of persons or to other aspects of public interest protection,...” might give the impression that one should consider aspects beyond the three essential requirements. Therefore, suggests clarifying this in the text that any requirement in Article R33 should be limited to only the essential requirements of the R&TTE Directive.
• The R&TTE-CA view’s is that the second sentence should also include EMF aspects. Arguably, the Decision text already covers this but it is certainly a point that should be brought out explicitly in the explanatory lead-up to the proposal. As for the specific proposal, it does not seem appropriate to delete any of the original text dealing specifically with health and safety matters so they would suggest that the proposal should be to extend it thus “...or to other aspects of public interest protection including harmful interference or effective and appropriate use of the radio spectrum.”

The ad-hoc working group concluded that Article R33 is essential in the case of e.g. interference caused by cumulative effects. In this case equipment can be compliant to the essential requirements. However a large number of equipment may lead to e.g. harmful interference. Article R33 allows taking action in this case.

The ad-hoc working group proposed to make the wording of article R33.1 more specific from “presents a risk [ ] to other aspects of public interest protection” to “…it presents a risk to the essential requirements of this Directive, it shall...”. (Recommendation 40)

2) France proposes to include in the new R&TTE Directive the description of “risk of harmful interference” as laid out in article 9.5 of current directive: “equipment, or types of radio equipment, which has caused or which the Member state reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands”.

The ad-hoc working group is of the opinion that clarification on the meaning of “dangerous product” and “risk” is necessary. It is yet unclear if the interpretation has to be specific for the R&TTE Directive or if can be a general interpretation in the new Blue Guide. The Commission’s view is that “Risk” and ”safety” is to be interpreted in a very broad sense, meaning that it is not only related to health, but as risk of not respecting one of the essential requirements in the Directives.

France is of the opinion that cumulative effects may also be considered ex-ante. In such cases they are taken into account in a spectrum harmonisation decision (example: the EC decision on 24 GHz SRR). The decision then sets thresholds (penetration rate, time limitation for placing on the market) that when reached call for a withdrawal from the market. There needs to be a tool that enables to take such a decision of withdrawal from the market.

Therefore the following new “safeguard measure” is proposed by France:
• ‘Products to be withdrawn from market under pre-defined conditions When the conditions of the placing on the market, as defined in spectrum harmonisation decisions (e.g. by RSCOM) of an equipment are met (such as a specified maximum penetration rate, or maximum number of equipment, or time limitation for placing on the market), measures” may be taken by TCAM (with approval from RSCOM) to withdraw from the market the specified type of equipment.’

However, since this discussion is out of the scope of this working group, the France proposal will be forwarded directly to the Commission by France though other means.
3.18 Article R34 Formal non-compliance

The ad-hoc working group agreed that some additional items should be added to the criteria for formal non-compliance: intended use of the equipment, missing information on limitation in use, lack of traceability information.

However, this is outside the scope of the work of the ad-hoc working group since it has nothing to do with the alignment with the NLF. The proposal could be picked up again when discussing the revision the R&TTE Directive.

The ad-hoc working group proposes that the following additions to R34 should be considered in the revision the R&TTE Directive:

- (f) information on intended use of equipment and usage restrictions does not accompany the equipment;
- (g) the traceability information is absent or not complete;

Germany proposes also to add the following criteria:

- “(h) all other administrative non compliance related to this Directive”

The ad-hoc working group noticed that these proposals will however have to take into account the results of the traceability ad-hoc working group. (Recommendation 41)
4 Annex II Conformity assessment Procedures

4.1 Integration of the new conformity assessment modules in the new R&TTE Directive

1) Taking in account the comments received by the European Commission during the consultation on the objectives of the revision of the R&TTE Directive and the discussions in the ad-hoc working group, it is recommended that the following Conformity assessment modules should be integrated in the new R&TTE Directive (Recommendation 42):

- Module A (internal production control) in replacement of the modules described in annex II and III of the current R&TTE Directive
- Module B (EC type examination - design type) + C (assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence, without examination of a specimen).
- Module H (full quality assurance) in replacement of the module described in the annex V of the current R&TTE Directive.

These conformity assessment modules may be applied according the following decision conformity tree:

2) In addition, the manufacturer should have the choice to use conformity assessment modules either from the R&TTE Directive or from the LVD and EMC directives to assess electrical safety respectively EMC aspects according following decision tree. (Recommendation 43)

- Modules from the LVD Directive (2006/95/CE) to assess the compliance with art. 3.1.a

- Modules from the EMC Directive (2004/108/CE) to assess the compliance with art. 3.1.b. This should be possible even if the EMC Directive explicitly excludes R&TTE products.
3) The majority of the participants to the ad-hoc working group were of the opinion that the intervention of a NB on a voluntary basis should not be regulated under the R&TTE Directive. The actual situation however show that a lot of manufacturers consult a NB even if this is not mandatory (product declared against harmonised standards is 80% of the cases were a NB is involved). The ad-hoc working group is of the opinion that accredited test houses and consultants could be involved in these cases and that this is not a task for Notified Bodies.

With reference to the Toys Directive, the ad-hoc working group proposed to insert a new article (R12a) dealing with applicable conformity assessment procedures. In the new R&TTE Directive, the conformity assessment procedures should not any more be linked with the type of product (terminal equipment, radio equipment, receiver …) but with the essential requirement that has to be assessed. (Recommendation 44)

The ad-hoc working group recommends the commission to consider below mentioned text Art. 12a mainly based on article 19 of the Toys directive and Article. 10.2, to be inserted in the new R&TTE

**Applicable conformity assessment procedures (Article R12a)**

1. Before placing a product on the market, manufacturers shall use the conformity assessment procedures referred below to demonstrate that the product complies with the essential requirements.

2. At the discretion of the manufacturer, compliance of the product with the essential requirements identified in article 3(1)(a) and (b) may be demonstrated using the procedures specified in Directive 2006/95/CE and Directive 2004/108/CE respectively, as an alternative to the subsequent procedures. He may use the internal production control procedure (Module A) set out in Annex II to demonstrate compliance with those essential requirements. At his discretion, he may also use the procedure set out in Annex III (EC-type examination carried out in the manner specified in the third indent of point 2 of module followed by the conformity to type procedure set out in Module C). He may also use the full quality assurance procedure (Module H) described in Annex IV.

3. Where in assessing the compliance of the product with the essential requirements identified in article 3(2) and 3(3), the manufacturer has applied harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering one or more essential requirements for the product, it may use the internal production control procedure (Module A) set out in Annex II to demonstrate compliance with those essential requirements. At his discretion, he may also use the procedure set out in Annex III (EC-type examination carried out in the manner specified in the third indent of point 2 of module followed by the conformity to type procedure set out in Module C). He may also use the full quality assurance procedure (Module H) described in Annex IV.

4. Where in assessing the compliance of the product with the essential requirements identified in article 3(2) and 3(3), the manufacturer has not applied or has applied only in part harmonised standards, the reference number of which has been published in the Official Journal of the European Union, covering the essential requirement identified in article 3(2) or 3(3) or where such harmonised standards do not exist, the product shall be submitted to the procedure set out in Annex III (EC-type examination carried out in the manner specified in the third indent of point 2 of module followed by the conformity to type procedure set out in Module C), at least in respect of those essential requirements. He may also use the full quality assurance procedure (Module H) described in Annex IV.
5 Description of conformity assessment modules

5.1 Annex II, Module A

The Module A described in Annex II of the NLF may be placed in Annex II of the new R&TTE Directive, with removing the description of the content of the technical documentation, which will be part of a new dedicated article (Art. 12b). (Recommendation 45)

Module A can be used to assess the compliance against article 3.1.a and 3.1.b. It can be used for assessing the compliance against article 3.2 and 3.3 only when harmonised standards have been fully applied.

Switzerland and France think that it should be specified that an available specific harmonised standard should be applied in preference to a generic one. R&TTE CA agreed that this could be reflected in the wording. However, this statement could be in contradiction with the general principles of NLF (Recitals 8, 9 & 11 of the Decision, for example).

5.2 Annex III Conformity to type based on internal production control (Module B (EC type examination - design type) + C (assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence, without examination of a specimen))

The ad-hoc working group recommends following text’s amendment to Module B (EC type examination - design type) + C (assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence, without examination of a specimen), which should to be included in Annex III of the new R&TTE Directive (Recommendation 46)

- **Module B** should be carried out by assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence, without examination of a specimen (EC type examination - design type). The provisions of this module in the new R&TTE Directive have to take this in account;

- **Paragraph 3** the description of the content of the technical documentation, which will be part of a new dedicated article (Art. 12b) has to be removed.

- **Paragraph 4**: The notified body has to take into account the relevant compatibility studies from European frequency planning bodies (as CEPT). He has also to take into account the state of the art presented in the current standards (harmonised or not). Some members of the ad-hoc working group expressed the view to have this inserted in this paragraph, other are the opinion that this aspect is already covered by the point 12 of R17 and part of conditions put on notified bodies.

- **Paragraph 5**: The last sentence of this paragraph has been amended to avoid prejudice to the obligation of the Notified Body to give information to market surveillance authorities. The words “notifying authorities” have been substituted by “point 8”. The agreed amendment removes that problem. It is also proposed to amend accordingly article 17.10 (see above).

- **Paragraph 8**: To have better information on products placed on the market without a full application of harmonised standards, a provision has been added which foresees that notified bodies shall automatically inform Commission, Member States and other notified bodies on EC type examination certificate when the manufacturer has not applied harmonised standards.

- For practical reasons, this requires all the parties concerned to support a common web-based notification system (e.g. CIRCA or OSN) and this should perhaps be reflected in the final legal text so as to avoid the limitations experienced with the OSN.
Observation: Belgium remarked that the obligation stated in paragraph 8 to inform also the other notified bodies of all the EC type examination certificates issued, could raise a problem of confidentiality and competition, especially if it concerns innovative products.

This issue may be also taken on board by the ad-hoc working group traceability.

- It is recommended to the Commission to explain, in the revised blue guide, how the information obligation laid down in the first paragraph of point 8 has to be carried out. This question is not only related to R&TTE Directive but is an horizontal issue.
- Notified body shall keep the relevant documents for 10 years after the assessment of the product.

5.3 Proposed text for amendments of Annex III

The ad-hoc working group recommends following text’s amendment of Module B (design type) + C, to be included in Annex III of the new R&TTE Directive (Recommendation 47)

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product, including examination of relevant compatibility studies from European frequency planning bodies (CEPT).

The ad-hoc working group is of the opinion that in those cases in which no compatibility studies are available, a solution should be found e.g. communication to the Commission, where the recently established Innovation group could be a good starting point.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis paragraph 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

8. ....

Each notified body shall inform the Commission, Members States and the other notified bodies of EC-type examination certificates it has issued and/or additions thereto in the case where harmonised standard has not been fully applied. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. ....

The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for 10 years after the product has been assessed or until the expiry of the validity of the certificate.

Observation: Belgium remarked that the obligation stated in paragraph 8 to inform also the other notified bodies of all the EC type examination certificates issued, could raise a problem of confidentiality and competition, especially if it concerns innovative products.
5.4 Annex IV Module H

The Module H described in Annex II of the Decision 768/2008/EC can be placed in Annex IV of the new R&TTE Directive with removing the description of the content of the technical documentation which will be part of a new dedicated article (Art. 12b). (Recommendation 48)

5.5 Content of the technical documentation

1) The ad-hoc working group is of the opinion that the provision on the content of the technical documentation shall be fully aligned with the provisions of the Decision 768/2008/EC. Some proposed provisions for article R12b may also be included in the obligations of the manufacturer. With the introduction of a new article about the technical documentation, the description of the technical documentation may be removed from the various annexes describing the conformity assessment procedures. The ad-hoc working group recommends the commission to consider below mentioned text, based on Annex IV of the Toys Directive the descriptions in the conformity assessment modules in the NLF, for a new Annex describing the content of the technical documentation in the new R&TTE Directive. (Recommendation 49)

(Article R12b) Technical documentation to be inserted in the new R&TTE directive

1. The technical documentation referred to in Article R2(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that products comply with the requirements set out in … [reference to the relevant part of the legislation]. It shall, in particular, contain the documents listed in Annex V.

2. The technical documentation shall be drawn up before the product is placed on the market and shall be continuously updated.

3. The technical documentation and correspondence relating to any EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

4. Technical documentation drawn up in accordance with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification shall be presumed to provide an adequate basis for assessment of conformity.

5. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

6. If the manufacturer does not comply with the requirements of paragraphs 1, 2, 3 or in cases where there are reasons to have doubts on the technical compliance, the market surveillance authority may require him to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer within a specified period in order to verify compliance with the essential requirement by applying the applicable harmonised standards. If the manufacturer is located outside the jurisdiction of the market surveillance authority, the market surveillance authority may reflect these expenses with the person responsible for the placing on the market under its jurisdiction.
2) The term “relevant” in article R12b.5: “Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.” should be clarified either in the R&TTE guide or better in the revised blue book.

This request should be based on proportionality and therefore relevant details on the technical documentation should be responsibility between the market surveillance authority and the manufacturer. (Recommendation 50)

3) Art. R12b.6 is based on art. 21.4 of the Toys Directive. This provision should not be implemented in the way that MSA cannot test products on manufacturer's expense in any other case than when there are shortcomings regarding TCF. Somehow it should be ensured that MSA will have possibilities to collect the testing costs from the manufacturer also in cases where there have been e.g. technical reasons for testing by adding “or in cases where there are reasons to have doubts on the technical compliance,” in this paragraph.

Art. R12b.4 mainly based on article 21.4 of the Toys Directive in the new R&TTE directive (Recommendation 51):

**Annex V Technical documentation to be inserted in the new R&TTE Directive**

The ad-hoc working group recommends the commission to consider below mentioned text, based on Annex V of the Toys Directive the descriptions in the conformity assessment modules in the NLF, for a new Annex describing the content of the technical documentation in the new R&TTE Directive. (Recommendation 52)

The technical documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

Therefore the ad-hoc working group recommends that the technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the product including: photographs or illustrations showing external features, marking and internal layout; versions of software or firmware affecting compliance with essential requirements; user information and installation instructions,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- copy of the declaration of conformity,
- copy of the EC-type examination certificate and annexes from the involved notified body,
- results of design calculations made, examinations carried out, etc., and
- test reports
Costs on an economic operator

Finally, the ad-hoc working group is of the opinion that National market surveillance authorities should also have the possibility to account the costs on an economic operator, if the manufacturer is located outside its jurisdiction, which is most of the cases for R&TTE products is applicable. (Recommendation 53)
6 Annex III Article R10 and EC Declaration of conformity (DoC)

6.1 Article 10 Declaration of conformity (Recommendation 19)

1. The EC declaration of conformity shall state that the fulfilment of requirements specified in … [reference to relevant part of the legislation] has been demonstrated.

2. The EC declaration of conformity shall at least contain the elements specified in Annex III of this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is placed or made available.

   **Remark:** The description “language or languages” is not precise enough and it should be clarified in the blue guide. This is not only a sectorial issue.

   This remark to the Commission is to ensure that it is not expected that manufacturers shall translate the DoC upon its issuance into all EU official languages (please consider that, only for the R&TTE-D, it has been suggested in point 5 below that the DoC shall accompany the product). It is feared that such interpretation might be taken by some Member States when the aligned Directive is transposed into the national level. However, such upfront translation requirement would create a disproportional burden for manufacturers without added value. When the manufacturer does not wish to translate the DoC upfront he must then provide the simplified form (see Annex IV). With the translated simplified DoC he can then also provide a full DoC in one of the EU official languages.

3. By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product.

   **4. A single declaration of conformity shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation.**
Proposed change: Adding this point 4 in Article R10.

Justification: this paragraph implements Article 5 of decision 768/2008/EC; not only a sectorial issue but more a horizontal issue. There is no need to deviate from the NLF for R&TTE products; therefore we recommend inserting this paragraph. Due to the fact that in some cases R&TTE products are falling under other sectorial directives as e.g. toys, we also strongly recommend that all other sectorial directives implement this paragraph.

Task for the Commission: Consider inclusion of article 5 of decision 768/2008/EC in all sectorial directives to avoid administrative burdens for the industry. Toys directive (2009/48/EC) should be accordingly updated. Consider making this article voluntary in order to avoid conflict with other sectorial directives like e.g. Toys which has been already published.

5. A copy of the full EC declaration of conformity (according to Article R10.2) shall accompany each product. As set out in Annex IV of this Directive, this requirement may also be fulfilled by a simplified EC declaration of conformity.

Proposed change: Adding this point 5 in Article R10.

Justification: The inclusion of either the full DoC or a simplified form with an Internet link reflects the situation in the current R&TTE Directive. This provision improves the traceability and helps the national market surveillance authorities (MSA) to fulfil their obligations laid down in the regulation 765/2008/EC. In such a way, MSA have an immediate access to the “passport” of the product and key information. It’s up to the manufacturer to decide between the inclusion of the full DoC or the simplified form with the Internet link. Independently of the chosen way, MSA should have an immediate access to the DoC without having to contact anybody.

Task for the Commission: The outcome of the WG TRAC should be considered. Consider this proposal together with the above comment in point R10.2 regarding the language of the DoC (i.e. since the DoC shall be provided with the product, it seems disproportionate to make an upfront translation of it. The simplified form should be translated in all languages as requested today by the Directive).
6.2 EC Declaration of Conformity, Annex III (Recommendation 19)

1. No … (unique identification of the product):

Proposed change: It is recommended to bring item 1 in line with EN 17050-1 which refers such a number for being unique for the DoC. This description is similar to paragraph 4 of this annex which would lead to confusions.

Justification: this requirement seems to be redundant with requirements in paragraph 4 of this annex.

2. Name and address of the manufacturer or his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.(or installer)

Proposed change: delete “or installer”.

Justification: the term “installer” is not defined in the decision 765/2008/EC nor in the R&TTE Directive. Inserting a new term without defining it could lead to uncertainties. Furthermore, this term has also been deleted in the Toy Directive.

4. Object of the declaration: identification of the product allowing traceability. It may include a photograph, where appropriate)

Task for the Commission: the term “where appropriate” should be clarified in the directive or in the guide.

Justification: It should be clearly defined when it’s considered appropriate to require a photograph and hence whether sentence concerning the photograph should be included here. This is not only a sectorial issue. There is no agreement amongst MSA on this point. Some MSA consider that a picture is needed if an identification of the product is not possible because of the size or the nature of the product. On the other hand, other MSA and Industry consider that this picture requirement would open a huge grey area like e.g. picture quality, quantity, shot angle, etc…, and would not bring any added value. EN ISO/IEC 17050-1 does not include images in the DoC.

5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation:

- R&TTE Directive (or 1999/5/EC)
- … (other pieces of legislation, when applicable)

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared. References should be listed with their identification numbers and version and where applicable the date of issue.

Proposed change: Adding the second sentence to this paragraph.

Justification: This sentence has been proposed to address MSA concerns when checking the standards used to demonstrate compliance with the Directive. A standard without numbers, date and/or versions is not enough. This inclusion is in line with the EN 17050-1.

7. Where applicable, the notified body … (name, number) … performed … (description of intervention) … and issued the EC-Type examination certificate:
8. Additional information

**Proposed change:** The possibility of requesting specific “additional requirements” for radio equipment was discussed.

The options discussed for the type of information:
- There is no need for this additional information
- Requesting frequency band(s) or discrete frequencies
- Requesting:
  - Frequency band(s) or discrete frequencies
  - R/F power linked to the frequency band(s)
  - Channelling linked to the frequency band(s)
  - Bandwidth linked to the frequency band(s)
  - Antenna gain linked to the frequency bands

If additional information is required, consideration was given as to where it would be located:
- In the DoC (in Annex III number 4, 6 or 8)
- In the accompanying documentation.

**Justification:** The evaluation of some characteristic phenomena’s in the area of radio equipment is needed for the work of MSA. The majority of MSAs are of the opinion that this additional information in some form should be included in the accompanying documentation. Some MSA considers the inclusion of this information in the DoC would reduce work evaluating the accompanying documentation.

Industry representatives expressed the view that the requirement for ‘additional information’ could prove to be an excessive burden, challenging its inclusion in the new R&TTE directive. However it was considered that the provision of certain technical information, limited to frequency bands only, may benefit market surveillance authorities in carrying out their functions and improve overall levels of product compliance. Other technical information would always be available, upon request, included in the Technical Documentation. Should there be a requirement that ‘additional information’ is supplied, this should be incorporated in the documents accompanying product. It is inappropriate to require that the DoC contains this data (the DoC is intended to demonstrate fulfilment of requirements specified in the R&TTE Directive (Article R10.1 of 768/2008/EC)).

A proposed text by the Industry to be eventually included in the revised R&TTE Directive:

*For radio equipment, the accompanying documentation shall specify the frequency band in which the equipment can operate. In case the equipment can operate in more than one band or in case the equipment has more than one radio interface, all the frequency bands shall be listed. In the case of terminal equipment with a radio interface that operates in licensed frequency bands and which only transmits under control of a network, the above frequency information does not need to include these licensed frequency bands.*

**Task for the Commission:** To consider this proposal taking into account the above arguments, firstly on the principle of requiring additional information for radio product, secondly on the extent of that requirement and thirdly on where the information, if required should be published.

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9. Signed for and on behalf of:

10. Place and date of issue

11. Name, function and signature
6.3 Simplified form of the EC DoC (Recommendation 19)

The requirement laid down in Article R10.5 is also fulfilled if the following simplified EC declaration of conformity accompanies each product:

**Hereby, [Name of manufacturer, or authorised representative, or importer, or distributor, as applicable], declares that this [type of equipment] is in compliance with the essential requirements and other relevant provisions of Directive XXXX/XX/EC.**

**Remark:** It shall be clarified in the R&TT-D Guide which person (i.e. manufacturer, or authorised representative, or importer, or distributor) should appear in each case (e.g. considering Article R6). This is to avoid that this is misinterpreted so that it would be requested more than one name in the simplified DoC. It is also proposed to the Commission to clarify, in the R&TT Guide, that the “type of equipment” should not contain the exact reference of the device if the document containing the simplified DoC can be uniquely related to the product ((such as a paper user manual with reference of the product and accompanying the product)

This simplified EC declaration of conformity shall be translated into the official language(s) of the Member State in which market the product is placed or made available.

Additionally, the full EC declaration of conformity shall be made available by one of the two following options:

i) Accompanying the product
   In this case the simplified EC declaration of conformity shall be complemented by the full EC declaration of conformity in one of the official languages of the EU.

ii) Available in an exact address.
   In this case the simplified EC declaration of conformity shall be directly followed by the exact address (Internet website or email address) where the full EC declaration of conformity can be obtained. The full EC declaration of conformity available at that exact address shall be in one of the official languages of the EU.

Following a request from the market surveillance authority of a Member State, the manufacturer shall provide a copy of the full EC declaration of conformity translated into the language of that Member State.

**Proposed change:** Adding this point Annex IV to the R&TTE Directive.

**Justification:** these are requirements already laid down in the current R&TTE Directive. Please refer to justification of proposal in Article R10.5.

**Task for the Commission:** The outcome of the WG TRAC should be considered.
7 Overview Recommendations

7.1 Outcome investigation

- All provisions of the Decision 768/2008/EC on the common framework for the marketing of products, and repealing council Decision 93/465/EEC were analysed by the ad-hoc working group alignment in accordance with the impact assessment procedures as stated in chapter 2. The ad-hoc working group has produced total 53 recommendations.

- The ad-hoc working group recommends the European Commission that following articles R7, R8, R11, R13, R14, R15, R16, R18, R19, R20, R22, R23, R24, R25, R29 and R30 of the EU decision 768/2008 may be included in the new R&TTE Directive.

- The remaining provisions were also detailed considered and needing modifications to be included in the new R&TTE Directive or in some cases in the new R&TTE Guide or new Blue Guide. The formal wording of the recommendations in the new R&TTE Directive might have to be adapted to the specific wording of the new R&TTE Directive, blue guide or R&TTE guide.

7.2 Overview Recommendations

<table>
<thead>
<tr>
<th>Provision or Article of the Decision 768/2008/EC</th>
<th>Nr. Rec.</th>
<th>It is recommended by the ad-hoc working group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision</td>
<td>Rec.1</td>
<td>That following provisions or articles R7, R8, R11, R13, R14, R15, R16, R18, R19, R20, R22, R23, R24, R25, R29 and R30 may be included in the new R&amp;TTE Directive.</td>
</tr>
<tr>
<td>R1 Definitions</td>
<td>Rec.2</td>
<td>That all provisions on definitions as laid down in Article R1 can be included in the new R&amp;TTE Directive. However, they have to be amended according to the wording of the R&amp;TTE Directive.</td>
</tr>
<tr>
<td>R1 Definitions</td>
<td>Rec.3</td>
<td>That the Commission is requested to consider if an alignment to “product” in all directives is needed/wanted</td>
</tr>
<tr>
<td>R1 Definitions CAS and NB</td>
<td>Rec.4</td>
<td>To merge the definitions of conformity assessment body and Notified body in one new definition</td>
</tr>
<tr>
<td>R1 Definition CAB and NB</td>
<td>Rec.5</td>
<td>To clarify what is meant by “conformity assessment body and notified body”. Therefore it is recommended to add or merge both definitions as a new definition in the new R&amp;TTE Directive</td>
</tr>
<tr>
<td>R1 New definition Conformity marking</td>
<td>Rec.6</td>
<td>To add a new definition in the new R&amp;TTE Directive on the term “Conformity marking” and to specify that this definition also includes “CE marking” and all other marking, required in the new R&amp;TTE Directive</td>
</tr>
<tr>
<td>R2.3 Definition “state of the Art”</td>
<td>Rec.7</td>
<td>To insert a new “Whereas” based on “whereas 13” of the current EMC Directive (2004/108/EC) dealing “State of the Art” as regards to the Electromagnetic compatibility</td>
</tr>
<tr>
<td>R2.3 Available technical documentation</td>
<td>Rec.8</td>
<td>That the EC declaration of conformity and the technical documentation should be kept available for a period of ten years</td>
</tr>
<tr>
<td>R2.4 Register of complaints</td>
<td>Rec.9</td>
<td>To clarify in the Directive or in the revised Blue Guide that the wording of the first paragraph of article R2.4 is also applicable if the manufacturer hasn’t fully used a harmonised standard to declare the conformity.</td>
</tr>
<tr>
<td>R2.4 Register of complaints</td>
<td>Rec.10</td>
<td>To clarify in the revised Blue guide which kind of register is needed and when it is deemed necessary to keep one.</td>
</tr>
<tr>
<td>R2.5 and R2.6 Manufacturer product identification</td>
<td>Rec.11</td>
<td>That clarification is needed with regard to the “where that is not possible”. The text of R2.6. (Identification product) in article R2.5 or otherwise by using the text stated in “whereas 25” of the Decision 768/2008/EC.</td>
</tr>
<tr>
<td>R2.7 Manufacturer product accompanied document</td>
<td>Rec.12</td>
<td>To use article 6.3 of the current R&amp;TTE directive regarding requirements for information accompanying the product. This should be added to the requirements for the manufacturer</td>
</tr>
<tr>
<td>Provision or Article of the Decision 768/2008/EC</td>
<td>Nr.</td>
<td>Rec.</td>
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<td>R2.8 Manufacturer measures on risk product</td>
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<td>R3.2(a) Manufacturer available technical documentation</td>
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<td>R4.2 Importers accompanied documents</td>
<td>see</td>
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<td>R4.3 Clarification when addressing not is possible</td>
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<td>R5.2 authorised representatives procedures</td>
<td>See</td>
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<td>R5.5 Distributors provide information to MSA</td>
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<td>R6 Obligations manufacturers apply importers and distributors</td>
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<td>R.9 Formal harmonised standards</td>
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<td>R.9 Competent body</td>
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<td>R10 and Declaration of Conformity (DoC)</td>
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<td>R12.1 Rules and condition for affixing CE marking</td>
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<td>R12.1 Position of additional marking</td>
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<td>R12.3 Identification of Notified Body</td>
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<td>R12.3 Notification Notified Body</td>
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<td>R17.6 Scope of a Notified body</td>
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<td>R17 Mutual Recognition Agreements</td>
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<td>R17.4 and R17.6 Task Notified Body as independent organisation</td>
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<td>R17.10 Information Request by a NB</td>
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<td>R17.12 Technologic knowledge NB</td>
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<td>R17.6 dealing requirements on NB</td>
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<td>R21 Accredited in-house bodies</td>
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<td>R26 Challenge of competence NB</td>
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<td>R27.2 That in case of including the new Conformity assessment procedures several sections</td>
<td></td>
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</tr>
</tbody>
</table>

To introduce a simplified form of Declaration of Conformity: To amend article 10 and the related Annex III (described in chapter 6 of this report) as stated in the Decision 768/2008 Decision in order to clarify the meaning of the DoC within the R&TTE Directive.
<table>
<thead>
<tr>
<th>Provision or Article of the Decision 768/2008/EC</th>
<th>Nr. Rec</th>
<th>It is recommended by the ad-hoc working group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational obligations Notified Bodies</td>
<td>Rec.34</td>
<td>of this article should be clarified. This can be done in the revised Blue guide</td>
</tr>
<tr>
<td>R.28 Obligation Manufacturer</td>
<td>Rec.35</td>
<td>That the following proposed text “Notified bodies shall fulfil other information obligation laid down in Annex III and IV” in order to cover other information obligation laid down in the conformity assessment procedures (Annex III and IV) will be added to article R.28.</td>
</tr>
<tr>
<td>R.31.1 Procedures dealing products risk</td>
<td>Rec.36</td>
<td>That an explicit reference should be added to the essential requirements of the R&amp;TTE Directive and therefore the words “present a risk to the health or safety of persons or to other aspects of public interest protection covered by this [act]” should read “present a risk to the essential requirements of this (R&amp;TTE) Directive as laid down in Article…. “. The current text of Article 9.5 of the R&amp;TTE Directive may be copied into the new R&amp;TTE Directive in order to solve this issue</td>
</tr>
<tr>
<td>R.31.5 Including article 9.2(a) present Safeguard measure</td>
<td>Rec.37</td>
<td>To add in Article 31.5 the case corresponding to incorrect application of the harmonised standard as mentioned under the current 9.2(a), it is suggested to add to article R31.5 the text of article 9.2(a)</td>
</tr>
<tr>
<td>R.31.8 Replacing article R.31.8</td>
<td>Rec.38</td>
<td>To replace in Article R31.8 the text as follows “Member states shall take the measures necessary to ensure that the non-compliant product is withdrawn from their market and shall inform the commission accordingly, without delay</td>
</tr>
<tr>
<td>R32 Community safeguard procedure</td>
<td>Rec.39</td>
<td>To align article R32.3 on short comings in the harmonised standards with article 9 of the 768/2008 Decision. (TCAM should be the only committee delivering the opinion).</td>
</tr>
<tr>
<td>R.33.1 Proposal specific</td>
<td>Rec.40</td>
<td>To make article R33.1 more R&amp;TTE specific the text of this article “presents a risk [ ] to other aspects of public interest protection” should be replaced to “…it presents a risk to the essential requirements of this Directive, it shall…. “.</td>
</tr>
<tr>
<td>R34 Formal non/compliance Related traceability</td>
<td>Rec.41</td>
<td>Due the fact of missing essential formal non-compliance the following criteria should be added in article R34 “(a) information on intended use of equipment and usage restrictions does not accompany the equipment and (b) the traceability information is absent or not complete.</td>
</tr>
</tbody>
</table>
| New Conformity Assessment modules              | Rec.42 | That in the new R&TTE Directive the following modules will be adopted:  
  • Module A (internal production control) in replacement of the modules described in annex II and III of the current R&TTE Directive  
  • Module B (EC-type examination - design type) + C (assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen).  
  • Module H (full quality assurance) in replacement of the module described in the annex V of the current R&TTE Directive. |
<p>| New Conformity Assessment modules              | Rec.43 | That the manufacturer should have the choice to use the conformity assessment modules either from the new R&amp;TTE Directive or the LVD and EMC Directives to assess electrical safety respectively EMC aspects according the mentioned tree conformity requirements |
| New Article Module                             | Rec.44 | The conformity assessment procedures should not any more be linked with the type of product (terminal equipment, radio equipment, receiver …) but with the essential requirement that has to be assessed. Proposed italic text of article R.12a (see chapter 4 of this report), based on article 19 of the Toys directive and Article.10.2, may be to consider for inserting in the new R&amp;TTE. |
| Module A                                       | Rec.45 | That Module A, described in Annex II of the NLF, may be placed in Annex II of the new R&amp;TTE Directive The description of the technical documentation will be part in a new dedicated article R12b as described in chapter 5. |
| Module B+C                                     | Rec.46 | To include Module B (design type) + C as Annex III of the new R&amp;TTE Directive with the amendments proposed in section 5.2. |
| Amendment text of module B+C                   | Rec.47 | To amend the text of original modules B+C as described in chapter 5.3 under points 4, 5, and 8. |
| Module H and Technical documentation           | Rec.48 | To include Module B+C as Annex III of the new R&amp;TTE Directive with the amendments proposed in section 5.2. The description of the technical documentation |</p>
<table>
<thead>
<tr>
<th>Provision or Article of the Decision 768/2008/EC</th>
<th>Nr. Rec.</th>
<th>It is recommended by the ad-hoc working group:</th>
</tr>
</thead>
<tbody>
<tr>
<td>New article R12b Content Technical documentation</td>
<td>Rec.49</td>
<td>will be part in a new dedicated article, described in chapter 5.2</td>
</tr>
<tr>
<td>R.12. b 5 and Technical documentation</td>
<td>Rec.50</td>
<td>That in order to be fully align with the NLF Decision, the text as described in paragraph 5.5 of this report and based on Annex IV of the Toys Directive should be added in the ne R&amp;TTE Directive.</td>
</tr>
<tr>
<td>R.12. b 4 Collect testing costs manufacturer</td>
<td>Rec.51</td>
<td>That the term “relevant “in article R12b.5: “the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that MS.” should be clarified either in the R&amp;TTE guide or better in the revised blue guide and based on proportionality and therefore relevant details on the technical documentation should be responsibility between the MSA and the manufacturer</td>
</tr>
<tr>
<td>Annex V Technical documentation</td>
<td>Rec.52</td>
<td>That in order to ensure that MSA will have the possibilities to collect the testing cost from the manufacturer etc... to add the text (chapter 6.5) article R12b.4 based on article 21.4 of the Toy Directive in the ne R&amp;TTE Directive</td>
</tr>
<tr>
<td>Possibility to account costs on an economic operator</td>
<td>Rec.53</td>
<td>National MSA should also have the possibility to account the costs on an economic operator, if the manufacturer is located outside its jurisdiction, which is most of the cases for R&amp;TTE products is applicable.</td>
</tr>
</tbody>
</table>