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NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY (MSG)

Title:	**CERTIF 2010-05 REV1 - Overview of market surveillance procedures (including safeguard clause mechanism) in the area of harmonised products**		
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Abstract:

The document provides an overview of the relations between the main provisions concerning market surveillance procedures contained in the NLF and discusses their applicability to existing harmonisation legislation.

As anticipated, with respect to its previous version this document contains additional text concerning:

– The link with procedure of formal objection to harmonised standards (see step 2)

– The special case of compliant products presenting a risk – Procedure in Art 33 Dec (see step 2)

– Relations between RAPEX and the Article 23 support system for 'serious risk' products (see step 5)

– Clarifications concerning the concept of 'provisional measures' (see step 6)

– Few clarifications on the link with the GPSD (see footnotes 5 and 7).

Keywords:	Market surveillance, safeguard clause, Rapex, ICSMS
References:	Regulation No 765/2008/EC of the European Parliament and of the Council Decision No768/2008/EC of the European Parliament and of the Council

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CERTIF 2010-05 REV1

OVERVIEW OF MARKET SURVEILLANCE PROCEDURES (INCLUDING SAFEGUARD CLAUSE MECHANISM) IN THE AREA OF HARMONISED PRODUCTS

1. INTRODUCTION

The New Legislative Framework (NLF) lays down a number of provisions in order to ensure that an effective and consistent system of market surveillance is established across the EU. The purpose of the document is to provide a first overview of the relations between the main provisions concerning market surveillance procedures contained therein, notably:

- The procedure to deal with **products presenting a risk** according in particular to Article 16(2) of the Regulation No 765/2008/EC (the "Regulation") and Article R31 in Annex 1 of Decision No 768/2008/ EC (the "Decision")

- Articles 20 and 22 of the Regulation concerning **products presenting a serious risk requiring rapid intervention**

- The **safeguard clause procedure** according to Article R32 in Annex 1 of the Decision.

The document also discusses the interpretation of applicable market surveillance provisions in the light of the principles underpinning the NLF.

2. THE LOGICAL SEQUENCE OF MARKET SURVEILLANCE PROCEDURAL STEPS

The table contained in this document shows the logical sequence of steps of market surveillance activities identified on the basis of the NLF provisions from any initial event triggering the need for closer scrutiny of products (e.g. ex officio initiative, reception of complaints, custom control activities), up to the outcome of a possible formal safeguard clause procedure. A series of intermediate steps are listed: the performance of compliance evaluation (step 2) and risk assessment (step 3), the request to economic operators to take corrective action and related measures (step 4), the imposition of restrictive measures (step 6), the notification of measures to other Member States and to the Commission of

the relevant measures (steps 5 and 7), the reaction of other MS to the notification received (step 8), the adoption of consistent measures by all Member State (step 10) or, alternatively the trigger of the safeguard clause mechanism (step 9), the consultation of relevant parties carried out by the Commission (step 11), the adoption of a Commission decision (step 12), the communication of measures adopted by Member States according to the decision (step 13) and any necessary follow-up in terms of revision of harmonised standards (step 14).

This representation of the relevant procedural steps in the NLF has the benefit to clarify the link existing between each of them in relation to the overall goal of ensuring effective and consistent market surveillance. In particular, the sequence of steps makes clear that the notifications of restrictive measures to Member States does not represent a stand alone step but is functional to the adoption of a **common approach among MSA** across the EU with regard to specific products presenting a risk. As a matter of fact, unless disagreement is expressed, following the reception of a notification, the Member States are in turn called to adopt appropriate measures (see steps 10 and 13).

Another important element is that, following the adoption of restrictive measures by market surveillance authorities (MSA) in the NLF, a distinction is made between the **communications of** those **measures** to the Commission and the other Member States and the formal safeguard clause procedure provided for in Article R32 of the Decision through which the Commission is called to decide whether the measures at stake are justified or not. This constitutes an important novelty because it means that certain procedural steps so far carried out under the **safeguard clause procedures** (communications of measures, exchange of Member States views) in the NLF are anticipated and take place at the stage when RAPEX (or ICSMS) notifications and reactions are exchanged. Moreover, this presentation of the different steps of the procedures to deal with risky products makes clear that a safeguard clause procedure only comes into play if, following a notification of national restrictive measures, the Commission or other Member States raise objections against those measures. This means that, while in the NLF all restrictive measures shall be notified, only a sub-set of notified measures – those against which objections have been raised – will trigger a safeguard clause procedure. This represents a fundamental difference with respect to the safeguard clause procedures currently applicable.

Furthermore, the table helps identifying commonalities and differences of market surveillance procedures for products presenting respectively a **risk serious or not**, showing that while the basic procedure remain identical, an important distinction concerns the notification of measures that for products presenting a serious risk shall normally[1] be done by using the RAPEX system, whereas for products presenting other risks shall be communicated by means of the information support system referred to by Article 23 of the Regulation.

Finally, the table also shows the link existing between the above mentioned procedures and other provisions of the NLF, notably **Article R33 and Article R9** in Annex 1 of the Decision containing respectively the procedure to deal with compliant products which present a risk to health and safety and the procedure to formally object to a harmonised

[1] Except when the reasons which prompted the restrictive measures or their effects are restricted to the national territory of the notifying Member State.

standard. By contrast, the provisions on formal non-compliance pursuant to Article R34 are not included in this overview.

3. INSTRUCTIONS TO READ THE TABLE

The table is organised as follows.

The sequence of logical steps to be taken by market surveillance authorities is provided in the **first column.** The steps of the *procedure to deal with product presenting a risk* are those from number 2 to number 10 and are outlined mainly according to Article 16(2) of the Regulation No 765/2008/EC and Article R31 in Annex 1 of Decision No 768/2008. The specificities relating to products presenting a *serious risk* requiring rapid intervention are indicated for each step on the basis of Articles 20 and 22 of the Regulation. The steps concerning the *safeguard clause procedure* are those from number 11 to number 15 and are defined according to Article R32 in Annex 1 of the Decision.

The **second** column recalls the legal basis of the main provisions on which is step is based.

The **third** column contains additional considerations as regards each of the steps identified in the first column. Some of them suggest that additional work may be needed to clarify the application of the relevant procedure.

The letter **D** in the table means "decision point" and indicates a stage where two or more options as regards the actual follow up of the procedure are possible; however it does not necessarily correspond to an administrative decision to be taken by MSA or other actors.

The words 'MS', 'MSA', 'Dec', 'Reg' stand respectively for 'Member States', 'market surveillance authorities', 'Decision' and 'Regulation'.

Table 1: Market surveillance procedural steps to deal with products presetting a risk and safeguard clause mechanism

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
1. (Presumably initial event suggesting to MSA that a product presents a risk to the health or safety of persons or to other aspects of public interests, in which case MSA move to step 2.)	*Various (e.g. Art 18 (2), Art 19 (1), Art 27 Reg.)*	*The need to carry out the evaluation of compliance may follow the occurrence of an accident, the reception of complaints, ex officio initiative of market surveillance authorities (including custom authorities controls of products entering the EU), as well as information from economic operators on products presenting a risk.*
2. When there are sufficient reasons to believe that a product presents a risk MSA carry out an **evaluation of compliance** with the requirements of relevant Community legislation. **D:** • If non-compliance is found, then move to following step • If products are in compliance, procedure stops here. (However, if, despite being compliant, products present a risk to health or safety of persons or to other aspects of public interests, then MSA apply procedure foreseen by Art R33 Decision).	*Art. R31(1) Dec* *Art 16(2) and Art 19(1) Reg*	***Meaning of 'sufficient reasons to believe that a product presents a risk*** *'The expression refers to the application of the precautionary principle and is meant to provide MSA with the flexibility necessary to launch the R31 procedure whenever deemed appropriate (e.g. in one of the cases mentioned above for step 1).* ***Compliance evaluation*** *MSA shall perform appropriate checks on the characteristics of the products. These can be both documentary and physical/laboratory checks, as necessary. Test reports and conformity certificates provided by economic operators shall be duly taken into account.* *The concept of compliance with essential requirements of Art. R31 includes both the case of failure of the product to meet requirements and the case of shortcomings in harmonised standards.* ***Link with procedure of formal objection to harmonised standards*** *It may be useful to clarify that when a MSA finds that non-compliance is due to shortcomings in harmonised standards and communicate this finding according to the relevant procedure (see step 5 below), this notification may also amounts in practice to a formal objection against harmonised standards. As a matter of fact, the communication will most likely trigger a reference by Commission to the Committee set up by article 5 of Directive 98/34 (see steps 9 or 12 and step 14).* ***The special case of compliant products presenting a risk – Procedure in Art 33 Dec.*** *Since applicable legislation defines the acceptable level of risk for a product, in principle there may not be products that at the same time comply with legislation and present a risk. Therefore this is a very exceptional case that is meant to account for important gaps in regulation (e.g. if new generation of products come on stream that present properties that are not fully*

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
		covered by existing essential requirements) *The procedure applicable in this case is provided for in Article R33 of Decision 768. It is observed that Art R33(1)-(3) set a procedure analogous to that of Art R31 as regards the adoption of restrictive measures and notification obligations. Furthermore, Art R33(4)-(5) contain provisions analogous to those in Art. R32 (safeguard clause).*
3. **Risk assessment** is carried out to answer the following questions: does product present a serious risk requiring rapid intervention? If serious risk requiring rapid intervention, in carrying out the following step MSA will follow the specific provisions of Artt. 20 and 22 of the Regulation.	*Article 20 Reg.*	***Concept of serious risk*** *There is no definition of 'serious risk' in NLF but Article 20(2) Reg. relates it to nature of the hazard and likelihood of its occurrence. Similarly the RAPEX guidelines define a 'risk' as '"a balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time". In this context, there are various situations that can be qualified as serious risk (e.g. a very severe injury[2] occurring with a likelihood of 1 out 10 000; a less severe injury[3] that is very likely[4] to occur).* *Article 20 of the Regulation also clarifies that the concept of serious risk requiring rapid intervention includes also "a serious risk the effects of which are not immediate".* ***Meaning of risk in harmonised sectors*** *The concept of 'risk' underpinning regulated sectors is closely linked to the legislator's choice of essential requirements. The latter indeed constitute important benchmarks for the risk assessment (see below). This also means that the fact that the legislator has accepted a certain level of risk should be taken into account.* *It is important to observe that for regulated sectors, the concept of risk encompasses not only risk to health and safety but also to other aspects of public interest protection (e.g. environment and consumers - see Art 3 Decision) by Community harmonisation legislation.* ***Risk assessment*** *-see CERTIF 2010-04 or* SOGS-

[2] Level 4 of injury (i.e. the highest level) according to the RAPEX Guidelines.

[3] Level 2 of injury (the lowest being level 1) according to the RAPEX Guidelines

[4] That is with a probability of at least 1%, according to the RAPEX Guidelines.

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
		MSG N016
4. MSA request without delay to relevant economic operators to a. take **corrective action** b. withdraw the product c. recall the product[5] d. stop or restrict supplying the product within a reasonable period. MSA also inform the relevant notified body. In case of <u>serious risk requiring rapid intervention</u>, MSA may in principle also move directly to step 6 below (i.e. can adopt restrictive measures without waiting that the economic operator takes corrective action to bring the product in compliance). **D:** • If non-compliance is not restricted to their national territory, move to following step • Otherwise move to step 6	*Art. R31(1) Dec, Art 16(2) and Art 19(2) Reg* *Article 20 Reg.*	***Corrective action by economic operators*** *Art R31(1) refers to 'corrective action to bring the product into compliance' with the requirements laid down in Community legislation. The focus of this step is indeed on corrective action to be taken by economic operator in order to remedy the issue of non-compliance of the given product. To that purpose, MSA have the possibility to require, among others, recalls and withdrawals of the product[6]. Any measure adopted at this stage should follow the principles of Article 21 of the Reg (see below for step 6).* ***Non-compliance not restricted to national territory*** *A notification to the Commission and other MS at this stage of cooperation between MSA and economic operators seems to be due only when 'non-compliance is not restricted to national territory' (Art R31(1). Nevertheless, in the light of Art. 16(2) it is considered that if a MSA adopts formal restrictive measures the latter should be notified also if the non–compliance only affects national territory (see step 7).*
5. MSA also **inform Commission and other MS** about results of compliance evaluation and actions that they required economic operators to take The economic operators are due to ensure that corrective action is taken throughout the EU In case of <u>serious risk requiring rapid intervention</u>, MSA notify to Commission any voluntary or compulsory measure according to Article 22 procedure	*Art. R31(2) and R31(3) Dec;* *Art 16(2) and Art 23 Reg* *Articles 20 and 22 Reg.*	***Geographical scope of non-compliance*** *This is relevant not only for MSA but also for economic operators, since they are due to ensure that corrective action is taken in respect to all the products concerned that they have made available throughout the EU.* ***Notification for products not presenting a serious risk*** *In the case products that <u>do not</u> present a serious risk the Commission and the other MS will be informed by means of the information support system indicated in Article 23 of the Regulation that should include, among other things, "information on non-compliance with Community*

[5] According to the Regulation, recalls can be imposed on economic operators through the adoption of formal measures only in case of products presenting a serious risk; however Article R31 in the Decision provides for the possibility to impose recalls when necessary for all products presenting a risk. In case of consumer products that are dangerous for the health and safety but do not represent a serious risk recalls, if not covered by sector legislation, can anyway take place under the GPSD Directive.

[6] Art 2 (14) and (15) of the Regulation clarify that 'recall' means a measure aimed at the return of a product already supplied to end users and 'withdrawal' a measure preventing the actual supply to end users. Definitions are in line with GPSD. It is noted that both recalls and withdrawals can either be put in practice as a result of cooperation between MSA and economic operators or follow the adoption of formal measures by MSA.

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
		harmonisation legislation", "identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with economic operators concerned and justification for action or inaction". ***Notification for products presenting a serious risk*** *According to Art 22 Reg., notifications for products presenting a serious risk should be made through the RAPEX system. The procedures currently laid down in the GPSD apply mutatis mutandis to the notification under Reg. For this reasons, although the handling of Art 22 notifications will remain as close as possible to the current RAPEX Guidelines, some adaptation of the latter will be necessary to reflect the new legal basis, the broader scope of products and risks categories and the link to the safeguard clause.* ***Relation between RAPEX and the Article 23 support system for' serious risk' products*** *- for future discussion* *The Article 23 information support system shall appropriately reflect notifications and information provided under Article 22. This suggests that at a certain moment (e.g. when the exchange of information in RAPEX on a given product is finished) product information should be archived in the general database.* *The use of RAPEX does not exclude the exchange of additional information on products presenting a serious risk by means of the Art. 23 platform if "not already provided under Article 22" (Art 23(2)).*
6. MSA verify that adequate corrective action has been taken **D:** • If so, move directly to step 8. • If not, MSA adopt appropriate **provisional measures** (recall or withdrawal of products or restriction/prohibition of their supply) [7], then move to following step.	*Art. R31(4) Dec;* *Art. 16(2), Art 18 (2)(c) and Art 23 Reg*	***"Provisional" measures*** *The fact that Art R31 speaks about 'provisional' measures does not mean that MSA can only adopt measures of temporary nature. MSA are entitled to adopt measure that last as long as necessary. The word 'provisional' accounts for the fact that in some national jurisdictions restrictive measures, in order to become definitive, need to be confirmed by a superior or a judicial authority. Furthermore, in general terms,*

[7] As regards consumer products additional measures such as warning and markings, temporary bans, recalls (if not covered by sector legislation)of dangerous products that do not present serious risks, can be adopted according to Article 8 of the General Product Safety Directive (GPSD). Further guidance in this respect is provided in the Working Paper on the relationship between the General Product Safety Directive 2001/95/EC and the market surveillance provisions of Regulation (EC) No 765/2008" that clarifies the relations between NLF and GPSD provisions in the light of the application of the l*ex specialis* principle.

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
		restrictive measures can be considered as provisional in the sense that their rationale is linked to the persistence of the problem of non-compliance: if at a certain moment this is solved, the measure can be withdrawn. It should also be recalled that in the context of harmonised products, restrictive measures that can be subject to a safeguard clause procedure may at a later stage be considered as unjustified. Therefore these measures when adopted can be seen as provisional in this regard too. ***Due process obligations*** *According to Article 21 Reg, when adopting the measures, MSA are bound, among other things, to:* o *Consult economic operator prior to adoption of measure; if impossible for urgency, then economic operator has opportunity to be heard asap after adoption* o *Communicate the measures to economic operators without delay* o *Withdraw or amend measures upon economic operator demonstrating that he has taken effective action*

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
7. **MSA inform Commission and other MS** about measures adopted, all necessary details and type of non-compliance (i.e. failure of the product to meet legislation requirements or shortcomings in harmonised standards) In case of serious risk requiring rapid intervention, measures adopted by MSA or that MSA intend to adopt are notified to Commission according to Article 22 procedure.	*Art. R31(4)-(5) Dec and Art 16(2) and Art 23 Reg* *Articles 20 and 22 Reg.*	***Notification procedures*** *Notifications procedures are the same as those detailed for step 5, respectively for products presenting a risk serious or not, except for the following: if the measures notified concern products presenting a serious risk, but the reasons for or the effects of the measure do not go beyond national territory, the notification will be done via the Art. 23 information support, rather than via RAPEX.* ***Notification of measures not yet adopted*** *Art 22 RAPEX notifications can also concern restrictive measures that a MS 'intends' to adopt, as it is already the case for RAPEX notification according to GPSD. It is worth mentioning that in principle a MS cannot be said 'to intend' adopting restrictive measure before the completion of the risk assessment, whose details will be transmitted to the Commission. Also, the risk assessment is a precondition to justify the need for rapid intervention and the use of the RAPEX procedure.* ***Link with safeguard clause procedure in non-aligned sector legislation -*** *for future discussion* *According to a number of sector harmonisation directives the notification of restrictive measures prompts the launch of the safeguard clause procedures that require the Commission to consult relevant parties and to issue an opinion or a decisions on the measures notified. The fact that according to the Reg the notification of measures should be done via RAPEX and ICSMS opens up the possibility to facilitating the functioning of current safeguard procedures. For instance, while notifications launching the safeguard clause procedure are currently sent via Permanent Representations, it would be possible to agree on working methods that could avoid duplicating information already provided via RAPEX.* ***Link with procedure of formal objection to harmonised standards*** *See comments provided for step 2.*

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
8. **Other MS** than the one having started the Community procedure inform Commission and notifying MS about any measures adopted and additional information available to them. In case of <u>serious risk requiring rapid intervention</u>, MS reactions are notified to Commission according to Article 22 procedure	*Art. R31(6) Dec and Art 24(1) Reg* *Articles 20 and 22*	***Follow-up to notification of measures - Reactions*** *MS are called to follow up on notification of other MS measure by verifying whether the same product has been made available on their territories and by adopting appropriate measures. This clearly broadens the effectiveness of the market surveillance activity launched by the notifying MS.* *Moreover, it is very important that other MS get involved by pooling together available information (e.g. relevant information on past controls and test).* *This follow-up is also in line with the indications already provided in the RAPEX Guidelines for reactions to notifications.* ***Procedures for the transmission of this information*** *Although not specified in the NLF, the transmission of this information should occur according to the same procedure of the initial notification (i.e. RAPEX and the Art 23 information support).*

SEQUENCE OF MAIN STEPS	***Legal basis***	*ADDITIONAL OBSERVATIONS*
9. Commission and other MS can raise **objections** to national measures notified within a certain period **D:** • If no objection is raised, move to following step • If no objection is raised and non-compliance is due to shortcomings in harmonised standards, move to following step and step 14. • If objection raised, move to step 11	*Art. R31(7) Dec*	***Link between objections and start of safeguard clause procedures in NLF (for aligned legislation)*** *The possibility for the Commission and other MS to object to national measures notified plays a crucial role because in the NLF it is a precondition for the launch of a safeguard cause procedure. Nevertheless it may be useful to consider the formal launch of the safeguard clause procedure as occurring some time after the actual communication of objections by means of RAPEX, the Art 23 information support or other. This is because it is not excluded that the disagreement expressed could effectively be handled in an informal manner. For instance according to working arrangements concerning low voltage products, when an objection is raised the Commission has 30 days to find informally an agreement between MS. Formal consultations are only launched after this period.* ***Procedures for communicating objections*** *- for future discussion* *Although not specified in the NLF, the communication of any objections to the measures of the notifying MS should occur according to the same procedure of the initial notification (i.e. RAPEX for serious risk and the Art 23 information support for other types of risk).*
10. Adoption of appropriate restrictive measures without delay by MS.	*Art. R31(8) Dec*	***Adoption of a common approach*** *The notifications of restrictive measures to Member States do not represent a stand alone step but is functional to the adoption of a common approach among MSA across the EU with regard to specific products presenting a risk. As a matter of fact, unless disagreement is expressed MSA in Member States having received the notifications are called to adopt in turn appropriate restrictive measures. Commission services in charge with the sector policies will monitor whether MS provide the necessary follow-up to notifications received.*
11. Commission opens **consultation** with the MS and the relevant economic operator and evaluate national measure.	*R32(1) Dec: Safeguard clause*	***Commission evaluation*** *In order to evaluate national measure the Commission should review both MSA conformity evaluation and risk assessment. In order to do so, the Commission could resort to expert advice.*

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
12. Commission takes a **decision** that is addressed to MS and communicated to economic operators. **D:** • If national measure is considered justified, move to step 13. • If national measure is considered justified and non-compliance is due to shortcomings in harmonised standards, move to steps 13 and 14. • If national measure is considered unjustified, move to step 15.	*R32(1) Dec: Safeguard clause*	***Commission decision*** *According to the safeguard clause procedure provided for in the NLF the Commission, at the end of the process, will issue a binding decision for all MS.*
13. **All MS** take the measures necessary to ensure that non-compliant product is withdrawn from the market, and inform the Commission accordingly.	*R32(2) Dec: Safeguard clause*	***Adoption of a common approach*** *The outcome of the safeguard clause procedure has the objective to lead to the adoption of a common approach among MSA across the EU with regard to products presenting a risk in the specific case when there is disagreement on national measures notified. Member States are then due to comply with Commission decision and will communicate the measures adopted to Commission services in charge with the sector policies.*
14. Commission informs relevant European **standardisation** bodies and brings the matter before the Committee set up by Article 5 of Directive 98/34/EC. The Committee shall consult the relevant European standardisation bodies and delivers its opinion without delay. **D:** In the light of Committee opinion, Commission decides to • Maintain the reference to the harmonised standards in OJ; • Maintain with restrictions the reference to the harmonised standards in OJ; • Withdraw the reference to the harmonised standards in OJ. The Commission also informs European standardisation bodies and, if necessary, request the revision of the harmonised standards concerned.	*R32(3) Dec: Safeguard clause,* *R9(2) Dec* *R9(3) Dec*	***Formal objection to an harmonised standard*** *Although Article R32(3) does not expressly refer to Art. R9, it appears clear that the case of application of the safeguard clause to national measures justified by shortcoming in harmonised standards falls within the scope of Art. R9.*[8] *Therefore this article provides complementary information on the procedure applicable in this case. It is worth noting that, since in this case the standards at stake are standards which have already been published in the OJ, the range of possible Commission decisions may be narrower than what is proposed by Art. R9.* *Any request for revisions of harmonised standards will follow normal standardisation procedures as laid down according to Directive 98/34/EC.*

[8] As a matter of fact, Article R9 concerns situations "where a MS or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in" the relevant legislative act. In this case, the Commission "shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. The Committee shall, having consulted the relevant European standardisation bodies, delivers its opinion without delay".

SEQUENCE OF MAIN STEPS	*Legal basis*	*ADDITIONAL OBSERVATIONS*
15. MS concerned shall withdraw the measure.	*R32(2) Dec: Safeguard clause*	

4. DISCUSSION WITH MEMBER STATES

Member States are invited to comment on the presentation of the sequences of relevant procedural steps for market surveillance activities provided in the document. They are also invited to indicate whether there are aspects of these procedures on which additional guidance is sought from the Commission.

Furthermore, a very relevant issue for discussion is that of the applicability of these market surveillance procedures. As a matter of fact, while the provisions laid down in the Regulation are applicable since 1 January 2010, those of the Decision will have legal effects only following the alignment of relevant sector legislation.

As regards the procedures allowing each Member State to deal with risky products, notify relevant measures and ensure a follow-up to the notifications received (see steps 1 to 8 and step 10), the delayed applicability of the Decision provisions does not seem to have serious implications in practice. This is because the Regulation already provides a strong legal basis to enable MS to take action against products liable to compromise the health and safety of users or, in any case, non-conform to the harmonisation requirements (e.g. Article 16(2), Article 18 and Article 20). Furthermore, the Regulation establishes clear obligations to inform the Commission and other Member States on restrictive measures adopted and to cooperate with the latter (e.g. Article 22, Article 23 and Article 24). In this context the provisions of the Decision can be seen as providing more specific information that help interpreting the Regulation provisions.

As regards the safeguard clause mechanism set in the NLF, however, the issue of the delayed applicability of the Decision does have important implications. As a matter of fact, on the one hand Article R32 of the Decision sets specific features for the safeguard clause procedure that in many respects are different from those in currently applicable harmonisation legislation[9]; on the other hand, the new features are not already reflected in the Regulation. Therefore, the safeguard clause procedure as identified in the table (i.e. steps 9, 12 and 13) is only applicable subject to the formal alignment of harmonisation legislation to the Decision[10] and the safeguard clause mechanism remains regulated by sector legislation that provides for a variety of procedures.

[9] Specific features of the safeguard cause procedure introduced by the NLF are the following: (i) safeguard clause mechanism is only initiated in case of disagreement between Member States on the national measures notified (i.e. step 9); (ii) national measure that are subject to the safeguard clause procedure can concern both situations where the products fail to meet legal requirements and where there are shortcomings in harmonised standards; (iii) at the end of the safeguard clause procedure the Commission issues a decision that binds all Member States (step 12).

[10] For instance, the procedure is applicable to the toys sector from early 2011.

As a consequence of this, among the matters to be discussed in the near future, there is the issue of how to manage the process of relevant notifications in the non-aligned sectors in such a way to avoid the risk of running parallel uncoordinated procedures respectively for safeguard clause and RAPEX (or ICSMS) communications. In particular, having in mind that the alignment will hardly occur before three or four years, the question arises whether it would be appropriate to define working arrangements to ease current safeguard clause procedures (e.g. avoiding adding a notification to formally launch the safeguard clause procedure when a RAPEX notification has already taken place and duplicating information already provided via RAPEX) within the framework of currently applicable legislation.