EU Member State Marketsurveillance & Function of ADCO-R&TTE

Jan Coenraads

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jan.coenraads@brynyago.com

Market Surveillance Purpose

That: Regardless of product origin:

``Compliance is ensured across the EEA.``

BECAUSE

- **All users are entitled to equivalent level of protection,**
- **”Eliminate unfair competition”.**

General concept of Market Surveillance

- **Essential tool for R&TTED enforcement**
- **Requires from MS to:**
  - **Take appropriate measures to ensure Market Surveillance obligations;**
  - **check that products meet the R&TTD;**
  - **bring non-compliant products into compliance, and apply sanctions when necessary.**

What is ADCO?

ADCO = **AD**ministrative **C**o-**O**peration Group

Why do we have ADCO R&TTED?

Administrative co-operation is an obligation of EU Member States to ensure an uniform application of the R&TTED.

Note: In principle each Directive has an ADCO Group (e.g for EMCD and LVD)

Market Surveillance is carried out on a national basis! There is no EU Police!

Administrative co-operation between national surveillance authorities therefore is absolutely needed to:

- increase the efficiency of surveillance;
- minimise different surveillance practices;
- reduce the overlapping of national surveillance operations;
- spread good surveillance practice and techniques across the Community;

ADCO Membership

- **Representatives of the Administrations of EU + EFTA + future EU Members**
- **Representatives of the European Commission, the EFTA Surveillance Authority and ERO as observers**
- **Representatives of Notified Bodies (R&TTECA), ETSI etc may be invited as guests to present information and exchange views.**

ADCO Confidentiality

RTTE ADCO meeting minutes are confidential.

ADCO report to TCAM is normally non-confidential, so that it can be published as part of the TCAM papers and is available to e.g. R&TTECA members

Members of RTTE ADCO have to respect the confidentiality of any information shared within RTTE ADCO (particularly details of individual surveillance cases under investigation)

But manufacturers information from market surveillance is not available for general public

Examples of ADCO Activities

Detailed Discussion of

Safeguard procedures

as prescribed in Article 9 of the R&TTED

- Providing an overview flowchart illustrating the whole procedure in details

Examples of ADCO Activities

Preparation and execution of a

First Pan-European Market Surveillance Campaign

- equipment (100 types per country) was randomly surveyed on compliance with the **administrative requirements** of the RTTED.

- Campaign period: Sept 2002 - Oct 2003

- 19 countries participating

RESULT: only 24 % of equipment was fully compliant with the R&TTED administrative requirements!

Examples of ADCO Activities

Preparation and execution of a

2nd Joint Cross-Border Market Surveillance Campaign

- Check **Technical documentation & provisions** of R&TTED.

  up to 10 different types of SRD should be surveyed, as SRD have been identified having shortcomings in the 1st EU campaign.
- Campaign period: Sept 2005 - June 2006.
- 18 countries participating.
- Evaluation of the test results is in operation at the moment.

2nd Market Surveillance Campaign

Why Choose SRD?

1. This kind of mass-market product is easy to measure;

2. the equipment is not so expensive to buy &

3. there is a large variety of these kinds of products available.

For more detailed information see CEPT Recommendation T/R70-03

Examples of ADCO Activities

- **Question:** Investigate the percentage of safeguard measures where CAB's were involved in the CAP.

- The 2nd campaign identified some cases,where a CAB involvement had an impact on the DoC of a product.
- The number of this cases was so small that no certain influence could be said to emanate from the CAB´s involvement on a general basis in the results of the campaign.
- Furthermore the manufacturer is responsible for the fulfillment of all provisions of the R&TTED. He is not obliged to follow the opinion of a CAB. So it seems impossible to give an reliable answer to this question.

Examples of ADCO Activities

- **Elaboration of a:**

Quick guide for manufacturers regarding obligations associated with the placing on the market of RTTE equipment

- taking into account the results of the 1st surveillance to improve the information status of manufacturers and retailers of R&TTE products.

- versions of this quick guide (in all EU languages) are available under

http://ec.europa.eu/enterprise/rtte/guide7.htm

Examples of ADCO Activities

Elaboration of a Guidance document for Market Surveillance Staff

- to give complementary special information in addition to the „Blue guide" on the application of RTTE Directive for more uniform and effective application and co-operation across the countries concerned

http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

- guidance regarding scope, administrative and technical compliance
- guidance about proportionate actions in case of non-compliance
- sum up of EU Commission and TCAM decisions for particular types of equipment

Note that:

Market surveillance does not take place during design and production, but:

Authority may check on the production premises (based on a non-compliance discovered) to:

- **verify whether a constant error can be established and/or**
- **prevent the further placing on the market of non-compliant products.**

Note that:

No products shall be excluded from market surveillance operations!

Including those subject to:

– any (voluntary) certification scheme or other voluntary initiatives,

–Involvement of a CAB

Safe Guard Clause

Follow up situations

Safeguard Clause

Remember that MS will:

- **Withdrawn from the market;**
- **Prohibit placing on the market or putting into service;**
- **Restrict the free movement:**

Of CE marked apparatus that does not comply

Reason for a Safeguard

Laid down in Article 8.3 of the Blue Guide

The safeguard clause is designed to allow the Commission to analyse the justification of national measures restricting the free movement of CE marked products (products presumed to comply with requirements).

Secondly, it provides a means to inform all national surveillance authorities about dangerous (non-conform) products …

Safeguard Clause Art. 9 R&TTED.

Only for "non compliant CE marked apparatus.

It can relate to particular 3 situations:

1. **incorrect application of Harmonised Standards; or**
2. **failure in the HS; or**
3. **non compliance with essential requirements (when not complying with HS)**

Reasons to invoke a safeguard procedure?

Laid down in Article 9 of the R&TTED

Where a Member State ascertains that apparatus within the scope of this Directive does not comply with the requirements of this Directive, it shall take all appropriate measures in its territory to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.

The Member State concerned shall immediately notify the Commission of any such measures…

Basic facts regarding Safeguard procedure

Safeguard clauses should be invoked if there are any national restrictions of placing R&TTE products on the European market (like sales ban)

Safeguard clauses have to be invoked also for non CE marked R&TTE products (exception from the rule written in the Blue Guide)

Safeguard clauses have to be invoked

➔ ***in cases of administrative non compliances (like missing CE mark, missing Alert sign, missing DoC, missing information requirements***
➔ ***in cases of technical non compliances (for EMC aspects, lack of efficiency frequency use, safety aspects)***

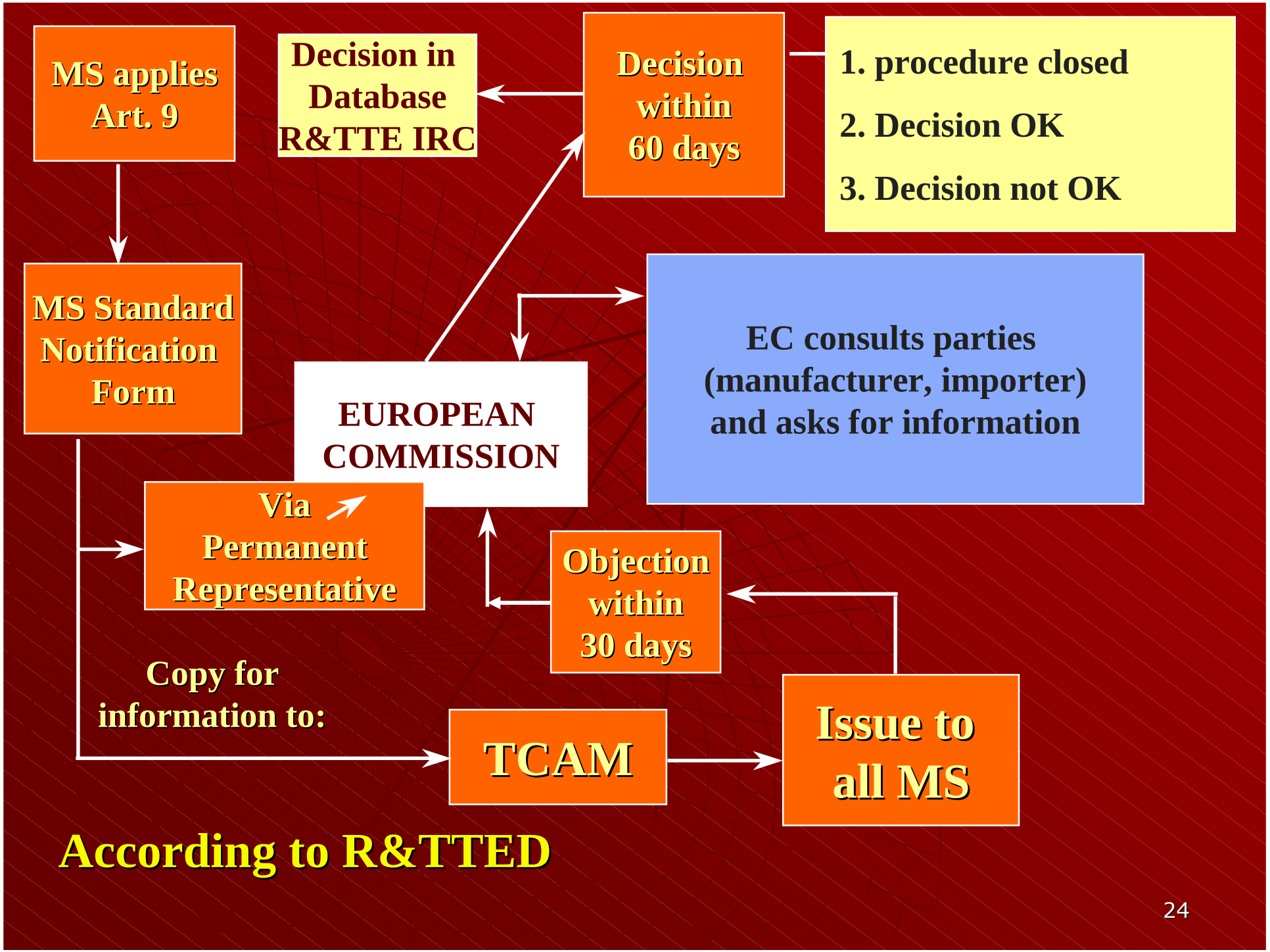
Reasons not to invoke a safeguard procedure

Applies in the case of an isolated error, limited to the territory of the Member State, that has discovered the non-compliance

If the manufacturer, the authorised representative, or other responsible person agrees with the Member State to:

➔ ***modify the product in such a way that it complies in the future with the applicable provisions.***

➔ ***stop immediate the placing of an imported non-conform product on the European Market.***


MS applies Art. 9
Decision in Database R&TTE IRC
Decision within 60 days
1. procedure closed
2. Decision OK
3. Decision not OK
MS Standard Notification Form
EUROPEAN COMMISSION
EC consults parties (manufacturer, importer) and asks for information
Via Permanent Representative
Objection within 30 days
Copy for information to:
TCAM
Issue to all MS
According to R&TTED

Number of Safeguards sent to the Commission

Member States perform some 200 investigations per year

However only a limited amount of cases are sent to the EU Commission.

2002	30
2003	16
2004	22
2005	18
2006	17

End of Presentation

Thank you for your attention

Any QUESTIONS ??