RED and market surveillance

Introduction

- Regulation (EC) No 765/2008 established a framework for market surveillance of products.
- Products have to fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.

Definition of "Market surveillance"

According Regulation (EC) No 765/2008, market surveillance is defined as :

- *'market surveillance' shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;*

RED essential requirements

- RED essential requirements are:
  - the protection of health and safety (art. 3.1(a));
  - an adequate level of electromagnetic compatibility (art. 3.1(b);
  - Effective and efficient use of radio spectrum (art. 3.2);
  - Additional requirements for certain categories (art. 3.3).
- Non compliance with one of RED essential requirements = risk to health, safety or any other aspect of public interest protection

Main elements

- Traceability information : manufacturer's and importer's names with address where they can be contacted (art. 10.7 and 12.3)
- Information on frequency band(s) and maximum transmitted power (art. 10.8)
- EU Declaration of conformity with each radio equipment (art. 10.8)

Follow-up and cooperation obligations

- Obligations for economic operators to:
  - take appropriate corrective action as soon as they consider or have a reason to consider that his radio equipment which they placed/made available on the market is non compliant;
  - immediately inform the national market surveillance authority when the non compliance is presenting a risk;
  - cooperate with national market surveillance authorities on their request;
  - be able to identify any economic operator who has supplied them with, and to whom they supplied radio equipment.

Specific provision (not yet active)

- From 12th June 2018, manufacturers of radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements may have to register them before placing them on the market (art. 5.1).
- Commission has to adopt delegated and implementing acts (art. 5.2 and 5.3)

General provisions addressed to notified bodies (NB)

- NB have to require the manufacturer to take appropriate corrective measures when they find that the essential requirements are not met. (art. art. 34.3, 34.4 and 34.5)
- Information obligation to notifying authority of any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval (art. 36.1(a))

Specific provisions addressed to NB – Annex III

- From Annex III, NB has to:
  - inform its notifying authority on EU-type examination certificates and/or any additions thereto which it has issued or withdrawn;
  - periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted;
  - inform the other notified bodies on EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted.

Specific provisions addressed to NB – Annex III (II)

- From Annex III, NB has to:
  - inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards have not been applied or not been fully applied;
  - on request of Member States, Commission or other notified bodies, provide them with a copy of the EU-type examination certificates;
  - on request of Member States or Commission provide them with a copy of the technical documentation and the results of its examinations

Specific provisions addressed to NB – Annex III (III)

From Annex III, NB has to:

- Follow the product:
  - regularly check the changes in the generally acknowledged state of the art (mainly reflected in the applicable HS);
  - investigate if those changes may affect the compliance of a radio equipment they assessed;
  - and, if yes, inform the manufacturer accordingly.

Specific provisions for market surveillance authorities

Specific provisions for MSA:

- Exchange of information between national MSA (via a common database – ICSMS)
- Union safeguard procedure
- RAPEX procedure
- Included in art. 15(3) and art. 16 to 29 of Regulation (EC) No 765/2008


MERCI!
THANK YOU!
FRAPAR.

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