



**NOTE TO THE SENIOR OFFICIALS GROUP ON
STANDARDISATION AND CONFORMITY ASSESSMENT POLICY – MARKET SURVEILLANCE
GROUP (SOGS-MSG)**

Title:	Draft CERTIF 2009-006 – Towards a methodology for dealing with the establishment of national market surveillance programmes as in Article 18(5) of the Regulation 765/2008		
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Abstract:			
<p>In the framework of the implementation of <i>Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products</i>, the SOGS-MSG (SOGS-Market Surveillance Group) was of the opinion that there is a need, at EU level, to elaborate an overall general approach for the elaboration of National Market Surveillance Programmes (NMSP). This is in relation to Article 18(5) which stipulates that Member States (MS) shall establish, implement and periodically update their market surveillance programmes.</p> <p>In this context it would be useful to have an overall framework at EU level aiming to help/support national authorities for the elaboration of their NMSP.</p> <p>Thus, the aim of this document is to identify the general elements for the purposes of the Regulation that could form the structure of NMSPs.</p> <p>This paper is based on a very succinct analysis of contribution produced by a number of MS.</p>			
Keywords:	Market surveillance, national market surveillance programmes, exchanges of information systems, cooperation, trainings, restrictive measures, statistics, ...		
References:	Regulation 765/2008; Directive 2001/95 (GPSD); RAPEX Guidelines; Decision 768/2008/EC		



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WORKING PAPER

**Subject: Towards a methodology for dealing with the establishment of national market surveillance programmes
- Regulation 765/2008 - Article 18(5)**

1. BACKGROUND

In the framework of the implementation of *Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products*¹, the SOGS-MSG (SOGS-Market Surveillance Group) was of the opinion that there is a need, at EU level, to elaborate an overall general approach for the elaboration of National Market Surveillance Programmes (NMSP). This is in relation to Article 18(5) which stipulates that Member States (MS) shall establish, implement and periodically update their market surveillance programmes.

Moreover, Article 18(5) states that “... *Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, [.....]. The first such communication shall be effected by 1 January 2010. [.....]. Member States may cooperate with all relevant stakeholders to this end.*”

The elaboration by MS of appropriate national programmes is crucial, notably because they will provide indicators for the efficient operation of market surveillance in the EU, and for the Commission such programmes will facilitate the evaluation of national market surveillance activities and allow for comparisons of organisation at the European level.

In this context it would be useful to have an overall framework at EU level aiming to help/support national authorities for the elaboration of their NMSP.

Thus, the aim of this document is to identify the general elements for the purposes of the Regulation that could form the structure of NMSPs.

This paper is based on a very succinct analysis of contribution produced by a number of MSs.

¹ OJEU L 218 of 09.07.2009, page 30 - 2 -

2. ORGANISATION OF MARKET SURVEILLANCE

Currently market surveillance activities are organised differently at national level. A preliminary broad survey shows that two main approaches are now followed by MS as regards the organisation of market surveillance activities:

- at horizontal and sectoral levels;
- mainly at sectoral level.

In this context, the NMSPs

Either (a): cover horizontal aspects of surveillance such as: the general objectives, the regional/local objectives, a general methodology, a risk assessment methodology, organisation of cooperation at national, EU and international levels, controls at borders, terminology, etc. and is supported by sector-specific programmes organised on the basis of particular targeted areas/products/risks, trends identified by concerns of industry, complaints and accidents, geographical region, facilities to perform primary controls, etc.

Or (b): focus mainly on sector-specific activities which are more or less well organised, but have the objective to control products on their particular market.

Although the above approaches are clearly different as regards the organisation of controls and information of the interested parties, the objective is to ensure that the results should be the same if the planned surveillance is correctly performed.

3. NATIONAL MARKET SURVEILLANCE PROGRAMMES -NMSPs

The following overall framework is suggested.

3.1. General/horizontal NMSPs objectives and elements

According to Article 16(3) “*National market surveillance (infrastructures and) programmes shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation*”.

For the purposes of the Regulation, a NMSP should be elaborated taking account of the following objectives and at least include and develop the following general elements.

The NMSP’s primary mission should be to identify situations/sectors/products that could pose a risk. Furthermore, it should foresee preventive actions in order to stop/avoid the placing on the market of unsafe or non-compliant products.

The national surveillance authorities have an obligation to establish systematic strategies to ensure effective market surveillance and other control activities and to make sure that they are transparent for the public and for the concerned parties.

At national level, market surveillance objectives are in principle wider than at sectoral and regional levels, and could cover general issues such as unfair competition and the economic protection of the consumer, including counterfeiting. This means that at national level the spectrum of surveillance activities could cover:

- harmonised and non-harmonised areas at EU level of safety aspects;
- general issues which contribute to making known the supply of a product and to safe purchases such as: clear and fair labelling information on products, fairness of commercial practices, control of correct prices, clear and fair public procurements and merger controls, control of cartels and dominant trading position, etc.
- issues that are common to different sectors/authorities, and suggestions on how to handle surveillance, coordination, overlapping, etc.
- inform, as far as possible, on the consequences of the restrictive measures that could be taken (see Article 21) and on the jurisdictional system put in place to sanction infringements (see Article 41).

3.1.1. *Surveillance activities*

In the context of Article 18(5) a NMSP should be general and sectoral/regional and be reviewed periodically and at least every four years.

It should in particular:

- (a) be annual or biannual,
- (b) fix the objectives and actions to be carried out [e.g. priorities in relation to risky sectors/products, or level of risk, or seasonal actions (e.g. Christmas, ..), description of the activities in relation to the type of action (inspection, reactive measure, joint project, etc.), organise the means to be informed on accidents/injuries or to receive complaints (see e.g. in France the “baromètre des réclamations et centre national d’appel/information”)];
- (c) be in line with the overall objectives of the Regulation, in particular with Articles 18 (1) to (4), 19 (1), 20, 21, 22, 24, 27.
- (d) be adaptable and renewable in relation to the market surveillance organisation and working methods that should be updated constantly to include new procedures in manufacturing and trade (e.g. risky products).
- (e) specify the general approach and procedures of the monitoring of products² and how sample-taking is targeted by product group.
- (f) be organised also in relation to the structure of the supply chain e.g. at the manufacturing point, wholesaler, retailer, internet, etc.
- (g) be balanced between proactive and reactive activities. Currently, controls are mainly based on investigations of accidents, complaints and other matters of evident concern found during routine inspections, or notification from economic operators.

² NB: The monitoring could be “basic” if at least e.g. 10% of the production quantity is monitored, or “high-level” if the monitoring is as comprehensive as possible e.g. 50%. In principle, effectiveness is reached if e.g. 14% of the production is monitored (average).

(h) be neutral/equitable in the same sector and between economic operators and imported or in-house manufactured products.

(i) set sectoral/regional priorities.

3.1.2. Control methodology

The Regulation requires that *“Market surveillance authorities shall perform appropriate checks of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples; When doing so they shall take account of established principles of risk assessment, complaints and other information.”* (see Article 19(1)).

Moreover, Article 20(1) requires that *“Member States shall ensure that products which present a serious risk ... Are recalled, withdrawn or that their being made available on their market is prohibited,...”* and Article 20(2) requires that *“The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence....”*

Therefore, the NMSP should give clear information on how to perform:

(a) the checks, and

(b) the risk assessment.

Details should be given of the general rules on how to proceed to take “adequate” samples and on their number (e.g. adequate samples that should be representative of the production process, if they are taken from the manufacturer/importer/distributor premises, etc.).

Article 19(1) already specifies the types of checks that could be performed and the sequence of their performance. Details could be given on this issue following the existing national legislation and administration.

The RAPEX Guidelines is the only document that develops at EU level established principles of risk assessment for consumer products. The Guidelines were designed for implementation of the GPSD and will now apply under the Regulation (see Article 22(4)). This means that it will have to be brought into line with the wider scope of the Regulation which includes products covered by Community harmonisation legislation and other risks than health and safety.

However, principles of risk assessment and a methodology should be generally applicable to all industrial products and should leave to market surveillance authorities the possibility to adapt to product/sector specificities or specific risks (e.g. environment). Taking account of the precautionary principle, this should be supported by scientific and technical expertise, best practices including results of joint actions, data on accidents and injuries available, etc...

In general, appropriate risk assessment could be of two types: (1) evaluation of the overall parameters of the safety aspects of a sector/product; (2) evaluation of the specific risk presented by a product. Moreover, the evaluation of the risk at national level could go further than the health and safety aspects, and could relate to the quality and fairness of the products, or to environmental issues.

The NMSP should also notably:

- not undermine nor forget to take into consideration innovation in the manufacturing and trade processes;
- establish the level of the checks (EU, national or local);
- grade priorities and be sure of the feasibility of the investigation/enquiry;
- have the appropriate means of action in relation to the importance of the problem;
- use the body of existing information.

3.1.3. Controls of products entering the Community market

According to Articles 27 to 29 of Chapter III on market surveillance, controls of products entering the Community market shall be carried out on the same basis as for products already placed on the EU market (see Article 27(1)). Thus controls at borders make up an integral part of market surveillance and the NMSPs should be developed accordingly.

This means that:

- the NMSP should reflect the national situation with regards to the different responsibilities of the authorities involved (without undermining the controls on imported products);
- the distribution of responsibilities between market surveillance and customs authorities should be clarified.
- the organisation of cooperation at national level should be in place in 2010 and a model of cooperation available;

The NMSP should meet the objective of enhancing controls on the safety aspects of imported products at the point of entry, avoiding their monitoring after their release when they are freely circulating in the EU market.

3.1.4. Powers and resources

One of the main pillars of the new market surveillance framework is the obligation on MSs to give market surveillance authorities (including customs) “... *the powers, resources and knowledge necessary for the proper performance of their tasks.*” (see Art. 18(3) and 27(1)).

On that basis market surveillance activities should have financial and human resources adequate to the activities to be performed and in relation to the planned monitoring activities, in particular in the NMSP.

3.1.5. Cooperation at national, regional/local and international levels

The NMSP will also ensure/organise cooperation according to Article 24 either at national level, including all interested parties, or at EU level, or with the Commission and the relevant Community agencies (e.g. ECHA, ERA, EMSA, etc.).

It shall demonstrate and develop the appropriate means and organisational measures to ensure that if assistance is required by a MS this shall be performed on an adequate scale (see Article 24(2)).

In this context, efficient cooperation requires, at least, that the following suggestions should be taken into consideration:

- enforcement responsibilities³ for specific sectors should be organised in order to avoid unnecessary checks or duplication or no controls at all;
- the organisation should establish dialogue between all relevant parties both in the same sector/region, and also across sectors/regions whenever relevant;
- the strengthening of cooperation with all interested parties including Notified Bodies and testing laboratories;
- participation in market surveillance activities currently performed at EU level such as the sectoral-ADCO groups or similar groups such as WELMEC or organised by Community Agencies, or by PROSAFE, but also at international level in forums such as ISO, OECD, UNECE, etc.
- participation in the development of cooperation programmes with third countries as under Article 26.

Moreover,

(a) the public/user shall be informed of the national market surveillance authorities and of their responsibilities (Article 17), and of any product presenting a hazard, so as to reduce the risk of injury or other damage (Article 19(2), 1st paragraph).

(b) provisions/organisation should be made for the economic operators to cooperate with national authorities regarding actions which could prevent or reduce risks caused by products made available by them.

(c) notifications of information on unsafe and non-compliant products coming from economic operators shall be evaluated and the appropriate follow-up ensured.

3.1.6. Information and communication

According to Article 24(1) MS shall ensure efficient cooperation and exchange of information internally, with other MS and with the Commission. Moreover, Article 23 creates the conditions to develop and maintain a general archiving and exchange of information electronic system i.e. ICSMS.

In this area, the main objective is to enhance information exchange and communication between all interested parties, which could notably include exchange of information on: priorities and working methods, categories of products under surveillance, all pertinent information available and in particular on testing reports, best practices, etc.

³ NB: “enforcement” could cover manufacturing and market surveillance controls.

At present the exchange of information may be made by using the ICSMS, RAPEX and RIF systems and also through other means as well. It should be examined how to bring greater coherence and simplicity to such exchange of information in the future.

3.1.7. *Statistics*

According to Article 18(2)(b) MS shall “*monitor accidents and harm to health which are suspected to have been caused by... products;*”. Statistics can be an important support to orient the organisation of market surveillance controls. They are essential to setting up priorities and to inform the public on unsafe products (see RAPEX statistics).

Therefore, it is essential to have a well-organised statistics system at national level. Links with EU and international IT tools such as ICSMS, RAPEX, IDB-Injury Data Base should be ensured. The NMSP will support and enhance the gathering and dissemination of statistics, and in particular it should promote their use.

The Commission could examine the possibility of developing with all MS the means of making national statistics comparable.

3.1.8. *Training activities*

Although provisions in Article 25(2)(a) concerning the development and organisation of training programmes and exchange of officials are addressed to the Commission who will ensure its implementation in the future, the NMSP should also provide for training activities at national level.

Training activities should include not only conferences and training courses, but also information and instructions delivered in leaflets, etc.

The NMSP should report on the envisaged national training organisation and activities. Some of them should also be opened to the public and interested stakeholders (industry, consumer organisations SMEs, etc.) to create synergies and avoid misunderstanding between all interested parties.

3.1.9. *Restrictive measures, corrective actions and penalties*

Articles 21 and 41 of the Regulation deal with obligations when a restrictive measure needs to be taken, and with penalties applicable to infringements (see too point 3.1., last bullet point).

These penalties should at least:

- be an effective deterrent to illegal activities, and punish rogue and protect legitimate stakeholders;
- be applied as uniformly as possible, taking account notably of the severity of injury or the degree of hazard;
- avoid discrimination in general, and in particular in relation to the origin of the product (imported, manufactured in the EU or national).

The NMSP should be transparent in this area and inform clearly and comprehensively what is the procedure used, and the consequences when restrictive measures (e.g. cooperation with

the economic operator concerned within not less than 10 days, etc.) are applied, and the sanction regime.

3.2. Sectoral NMSPs elements

For the purposes of Article 18(5)(6), a general sectoral NMSP should not contain details on the planned tests and on how the inspections should be carried out for confidentiality reasons.

For the above purposes, the following suggestions should be applicable to every industrial sector:

- include a comprehensive and clear description of the sector or product(s) concerned by category, spectrum of products, rationale, standards applicable, etc. of the legislation applied (EU or national).
- take account of or make reference to the horizontal NMSP as a whole or to specific parts of the horizontal programme (see point 3.2), where appropriate;
- cover all specific risk-based elements;
- describe the commercial situation and means of trade;
- target all products and include checks at external borders.

As regards the organisation of sectoral controls, they should be organised on the basis of the following elements:

(1) Documentary checks (see Article 19(1))

The documentary checks or administrative surveillance should include all the activities to check a product/sector by using only the documentation available. This should include checks of documents:

- either as provided for in the legislation, i.e. manufacturer's declaration of conformity (DoC), technical documentation (summary including, in particular, the essential technical data), notes, certificates of conformity etc. When the Directive does not require a DoC, the documentary check will consist of the examination of reports as submitted by the person responsible for placing the product on the market, in line with the customs declaration. It could also be necessary to check if the correct conformity assessment procedure has been applied.
- or other documentation such as photos, complaints, accidents reports, etc.

(2) Physical checks (see Article 19(1))

This involves visual monitoring of the product, namely:

- An examination of the product and check on the presence of CE marking and of other markings and possible regulatory labels;

- A check on the presence of the name and of address of the manufacturer or of the person responsible for placing the product on the market;
- A check of undue or incorrect affixing of the CE marking or of other regulatory markings (e.g. for toys the indication of the age of the child).

(3) Laboratory checks (see Article 19(1))

Laboratory tests can be necessary to check the technical conformity of the product. These tests can be decided independently of any potential information on non-conformity. They can also follow from either controls of the customs authorities or factory inspectors on site, or following accident indication or complaints.

(4) Sampling criteria

When a market surveillance authority decides to perform physical and/or laboratory checks they have to take the necessary/adequate samples.

The sampling criteria have to be supported by e.g. the price, the level of the risk, number of notifications received in RAPEX or in ICSMS, the complaints and accidents, etc.

(5) Follow-up

Each evaluation of the safety and conformity aspects of a product should be submitted to an appropriate follow-up. Appropriate actions have to be taken in relation to the severity of the results.

The follow-up action should include informing the interested parties (public authorities, economic operator, consumer organisations, etc.), and decisions to be taken (e.g. withdrawals, sales ban, warning in mass media, etc.).