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PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU

(Text with EEA relevance)

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1. INTRODUCTION

The surveillance of the internal market for products is, in practice, an enormous challenge: the range of products to be controlled is very wide, many are imported from outside the Union, Member States have limited resources to perform checks and inspections and the need for controls in the Member States depends on various factors, such as the geographical and administrative structure of a country.

Performing market surveillance requires a sound infrastructure, efficient organisation and specialist knowledge. The combination of these elements is essential to achieving the twin objectives of protecting the citizen and ensuring fair competition. The organisation of market surveillance has to be frequently adapted to cope with evolving needs and a changing industrial environment.

The core of market surveillance is a chain of interdependent processes such as inspections, sampling, laboratory testing, interpretation of results, risk assessment, decision making, intervention and ensuing legal procedures which may involve corrective measures or even sanctions. The multi-annual market surveillance action plan is one of the 50 action points listed in the "Single Market Act"[1]. It will introduce a number of objectives to be pursued and measures to be taken to achieve its political objectives and eliminate market dysfunctions. The Single Market Act II[2] reiterates the need to improve the safety of products circulating in the EU.

This plan aims to fill gaps and make the surveillance of the single market for products (with the exception of food, feed and medicines) more efficient and operational to properly implement the relevant provisions of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance[3] and Directive 2001/95/EC of the European Parliament and Council on general product safety[4]. It is part of a wider package that also includes proposals for a Regulation on Consumer Product Safety and a Regulation on Market Surveillance. The plan complements – and must be read in conjunction with - these initiatives but, pending the final adoption of these legislative proposals, it builds on the

1 COM(2011) 206 final
2 COM(2012) 573 final
3 OJ L 218, 3.8.2008, p. 30
4 OJ L 11, 14.1.2002, p .4

existing set of rules and programmes[5]. It also takes into account the problems outlined in the impact assessment that accompanies this package.

The Commission intends to implement this plan with effect from its adoption, until 2015. At that time, it will assess whether a future multi-annual plan is necessary. However, not all actions will start at the same moment and the duration of each action will be dictated by its specific needs.

The main objective of this plan is to outline the non-legislative action that the Commission will take to reduce the number of unsafe or non-compliant products and ensure the efficiency and effectiveness of the surveillance of products both within the Union and on entry into the Union.

2. EFFICIENCY AND EFFECTIVENESS GAINS WITHIN THE EU

Market surveillance authorities must be properly organised and equipped to cope with the obligations and requirements of the relevant Union legislation. However, experience has revealed gaps in the Union market surveillance framework. To conduct effective and efficient market surveillance, responsible national authorities need a sound infrastructure, good organisation, appropriate legal powers, suitable facilities and equipment and competent and skilled officers, benefiting from high quality training.

2.1. Pooling of information stemming from investigations

To verify whether a product poses a risk or is non-compliant with the applicable requirements, tests and checks are usually required in order to provide information for the risk assessment. Tests entail high costs. Sometimes competent authorities lack the technical expertise to properly perform tests and also interpret the test results. Appropriate coordination, cooperation, training and information sharing is therefore essential in this area.

Action 1: Facilitate the 'portability' of test reports in the Union

The Commission will promote the use, among the relevant market surveillance authorities including those responsible for external border controls, of results of tests already performed in one Member State by other Member States and will also facilitate their distribution via ICSMS.

Sharing information between market surveillance authorities and with customs across the EU is essential to avoid double work. Information Technology systems are the best way to achieve this since they enable efficient work flows and allow swift and easy retrieval and

[5] The Union financing which may be necessary for specific actions will be granted in accordance with the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [OJ L 218 of 3.8.2008, p.30], Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013) [OJ L 404 of 30.12.2006, p. 39] and, possibly, the future Regulation of the European Parliament and of the Council on a consumer programme 2014-2020, and Decision No 624/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing an action programme for customs in the Community (Customs 2013) [OJ L 154, 14.6.2007, p. 25] or its successor. All the actions in this plan are compatible and coherent with existing or proposed legislation.

exchange of information. The new IT platform GRAS-RAPEX[6] is used for the Member States to submit RAPEX notifications. On the other hand the ICSMS[7] tool offers fast and efficient communication means for market surveillance authorities to exchange information within a short space of time. ICSMS is not an alert system but a market surveillance general archiving and information-sharing tool that aids in establishing a co-operation mechanism among authorities and a general information tool on market surveillance. The ICSMS could also be enlarged for the exchange of information between customs authorities as well as with the national competent authorities.

Action 2: Maximise the benefits of ICSMS

ICSMS will be developed further to collect, store and exchange information and best practices among all the actors directly concerned. This will include eventually the publication of test results, results of joint actions, guidelines and guidance for training of market surveillance authorities, case studies, statistics and overall information on market surveillance for products.

Action 3: Create synergies between GRAS-RAPEX and ICSMS

GRAS-RAPEX and ICSMS have very distinct functions and are therefore kept separately. The Commission, in regard of the GRAS-RAPEX and ICSMS distinct objectives, will develop, however, synergies between both systems.

In addition, data related to accidents and injuries caused by unsafe products should feed into the market surveillance efforts. Although Regulation 765/2008 (Article 18) obliges Member States to monitor accidents, little has happened in practice, considering the many practical difficulties to establish a reporting system that could be helpful for all authorities and economic operators.

Action 4: Assess the cost/benefit of an EU accident/injury database (AIDB)

The Commission will examine the feasibility of a public Consumer Product Safety Information Database, which could include a platform for complaints and injuries. It will take into account the achievements made by EUROSAFE, OECD and other relevant tools available in this area[8].

2.2. A common approach to risk assessment

One of the most challenging activities for market surveillance authorities is the identification and correct assessment of the risk presented by a product. To facilitate the effectiveness and efficiency of the risk assessment, the Commission has already developed a risk assessment methodology available in the RAPEX Guidelines (OJEU No L 22 of 26.01.2010). However, this methodology has to be updated and cover all risks.

Action 5: a EU general risk assessment methodology for products

6 GRAS-RAPEX replaced the old IT system RAPEX-REIS and extended the scope of RAPEX to professional products and to other risks than health and safety.

7 Information and Communication System for Market Surveillance (www.icsms.org)

8 As for example sector-specific data collection tools like the Community Database on Road Accidents established by Council Decision 93/704/EEC.

The Commission will complete and update the general risk assessment methodology available in the RAPEX Guidelines so that they cover the other risks.

2.3. Performance Benchmarks for market surveillance

The study "Future of Market Surveillance"[9] showed that there is very little performance information regarding the market surveillance activities of Member States available, and accurate benchmarking is impossible. It also suggested that Member States find the provision of information an unnecessary burden, but probably as a result of not recording the required information in an easily accessible format.

In order to allow for benchmarking and comparability of indicators of market surveillance performance in Member States the European Commission established in 2008 a data collection tool dedicated to collection of data which measure the key activities of national authorities in charge of product safety enforcement. However, despite a continuous effort on the quality and scope of the enforcement indicators, the accuracy and the usefulness of the information collected as well as its comparability - which allows the identification of strong and weak links in the EU market surveillance enforcement framework - remains limited. In addition, there is no reporting on the results of border controls. The Administrative Cooperation Groups (ADCOs) should be used for such benchmarking, in their respective areas of competence.

Action 6: Developing Key Performance Benchmarks for market surveillance

The Commission will ensure the improvement of the data collection system and determine, together with the market surveillance authorities, the most important key relevant enforcement indicators that should be collected in the medium term. The Commission will also collect data from the Member States on the results of border controls from 2013 and publish an annual report from 2015.

2.4. Facilitate controls for high tech and innovative products

It is generally recognised that it is very difficult to perform safety controls on products that hold dangerous substances such as cadmium and lead, or for high technology products like the electronic weighing instruments. The control of the conformity of these categories of products can be done only by destroying the sample, very often incurring high costs and involving difficulties in demonstrating *a posteriori* non-compliance. The products concerned are covered by EU legislation, and are very numerous. At present, given the difficulties described above, it is not clear if these products are controlled only by documentary and physical checks, but also by laboratory checks on the characteristics of the products - as required by Regulation 765/2008[10].

Action 7: Examine the feasibility of safety and compliance controls for high tech and innovative products

The Commission will examine the feasibility of facilitating the safety/compliance controls by national authorities for high tech and innovative products. This will have a twofold objective (a) facilitate the checks by Member States and (b) avoid a situation where these products are

[9] The future of market surveillance in the area of non-food consumer product safety under the General Product Safety Directive, Final Report, March 2011, BSI Development Solutions, May 2011, p. 13.

[10] See Article 19(1)

never properly checked as a result of technical difficulties. The feasibility will take into account the specificities of SMEs.

3. A CLOSER COOPERATION THROUGHOUT THE UNION

The rapid integration of the single market for products, the fact that more and more transnational businesses are developing and offering a wide range of products in several Member States, the development of e-commerce across borders in Europe and the growing number of imports of products manufactured outside the EU, means there is a need for more cross-border cooperation on market surveillance. It is therefore important that the organisation of market surveillance activities mirrors developments on the European product market, inter alia to ensure the sharing of information on inspection results and to avoid the repetition of tests.

3.1. Coordination of cross-border surveillance activities

The accompanying legislative proposal for a Regulation on Market Surveillance aims to strengthen and streamline European procedures for the exchange of information about unsafe or non-compliant products, through a stronger RAPEX procedure, and the integration of 'safeguard procedures' for certain products that often bear the CE marking. Nevertheless, better exchange of information also depends on more and increasingly coordinated cross-border market surveillance activities, coordinated planning and mutual assistance.

To this end, the proposal for a Regulation on Market Surveillance suggests establishing an 'EU Market Surveillance Forum' and an Executive Secretariat to assist it, with the participation of all Member States, to facilitate the coherent implementation of the activities covered by this plan or in the relevant EU legislation. The ADCOs will also be part of this EU Market Surveillance Forum.

Action 8: Prepare the creation of an Executive Secretariat

The future EU Market Surveillance Forum needs organisational assistance to perform its tasks. The Commission will establish an Executive Secretariat that will assist the EU Market Surveillance Forum.

3.2. Joint enforcement actions

The creation of the Internal Market ensures that products circulate freely across the Union. Unfortunately, many market surveillance activities are still limited to the national territory and their results are not always made available to other authorities. More coordination of the practical enforcement work is paramount to achieve a level playing field for economic operators and an equal level of consumer protection across the EU.

Action 9: Joint enforcement activities

The Commission will provide financial support for joint enforcement actions, allowing market surveillance authorities and customs to pool resources and expertise and to apply SME-friendly methods. The main objective of this initiative is to enhance the efficiency and effectiveness of the surveillance system in Europe, as well as to improve the coordination of the practical enforcement work carried out in relation to product categories or other priorities.

3.3. Exchanges of officials

To encourage market surveillance authorities to share and gain experience and expertise in product safety and market surveillance mechanisms, the Commission will provide financial support for exchanges of officials between Member States.

Action 10: Exchange of officials

The Commission will provide financial support for exchanges of officials in the area of non-food consumer products and service safety.

3.4. Closer European cooperation on market surveillance

European cooperation on market surveillance for products that are subject to Union harmonisation legislation usually takes place through informal groups of market surveillance authorities. They meet in the informal and sectorial 'Administrative Cooperation' groups, known as ADCOs, which discuss market surveillance problems in their area. These groups are often chaired by a representative of a national market surveillance authority. However, as the organisation of the meetings of these groups represents a considerable administrative challenge for the chairperson, while many of the market surveillance authorities cannot attend these meetings as a consequence of budgetary constraints, the Commission proposes to increase its support for these groups.

Action 11: More support for 'Administrative Cooperation groups' (ADCOs)

The Commission will provide financial support towards the administrative functioning of most of these groups so that the administrative burden of the organisation of these meetings can be reduced. The Commission will also discuss with the ADCOs the most cost-efficient method for the reimbursement of, or financial support for the travel costs of market surveillance authorities that wish to attend the meetings of the selected groups.

3.5. Products sold on-line

E-commerce is expanding rapidly and constitutes a new challenge for market surveillance authorities. The public consultation on the revision of the General Product Safety Directive indicated that market surveillance activities with respect to products marketed online take place in a fairly incidental, fragmented and uncoordinated manner[11].

As a consequence, the level of protection and legal support of consumers and other users against risks posed by unsafe products sold on-line lags behind the level of protection provided in respect of other distribution channels. Consumers often buy products online and face problems if the product is unsafe or non-compliant. Unsafe products that were withdrawn and recalled from the EU market may still be available to final users via the Internet.

Action 12: Products sold on-line

[11] According to the public consultation (performed in summer 2010), only half of the national authorities have specifically monitored products sold online at a certain point of time during the last three years. A large majority of those national market surveillance authorities which performed some monitoring of products sold online had difficulties indicating the number of websites checked, the number of products targeted or the number of products sampled for further tests.

The Commission intends to:

- study the ways in which e-shops selling consumer products operate, including the location of large e-commerce operators, e-commerce supply depots and e-commerce supply routes, in particular if products are distributed to the final consumer directly from third countries and the role and importance of SMEs in the e-commerce supply-chain;

- establish, together with the Member States, a common understanding/approach of the ways in which the surveillance of products sold online should be performed in the Union and produce guidance on the enforcement of the rules for products sold online, especially in cross-border situations that require cooperation between the authorities of different Member States or third countries;

- collect information from the Member States enforcement authorities/agencies on such enforcement activities;

- educate consumers and define the roles and responsibilities of the relevant parties (authorities, economic operators and consumers) in the form of short, simple and clear public information statements.

3.6. A continuous European dialogue with stakeholders

Market surveillance concerns all parties in the supply chain, and needs the input of consumer organisations and businesses, and especially small and medium-sized enterprises (SMEs), relating to their problems and concerns. SMEs play a key role in shaping Europe's economy. However, the administrative burden related to market surveillance controls is comparatively heavier for SMEs than for major businesses.

Under current EU legislation businesses must take action if they know or ought to know that their products present a risk. They are obliged to inform the national authorities, who use the RAPEX system to ensure that all Member States are made aware and take appropriate action on their territories. However, European organisations representing the interests of consumers, SMEs and other businesses have not yet been systematically involved in European efforts to improve market surveillance. This should change.

The proposal for the Market Surveillance Regulation envisages an active role for European businesses and consumer organisations in the European Market Surveillance Forum. Until then, it would be helpful for market surveillance to involve them more closely in identifying problems, listing categories of products that need closer attention and finding effective solutions.

Action 13: The active involvement of European organisations representing consumers, SME and other businesses

Dialogue and cooperation with organisations representing consumers, SMEs and other businesses is essential. They know the products and the risks that they can present to users. The Commission will improve channels for providing feedback, input and suggestions on market surveillance in the Union and on the implementation of this multi-annual plan. This will help to identify new needs for market surveillance and should address the specific concerns of consumers, SMEs and other businesses. Market surveillance authorities could be included, and also where appropriate, their colleagues in third countries.

4. IMPROVING SUPPLY CHAIN SUPERVISION

Market surveillance is the responsibility of the relevant national market surveillance authorities. However, all parties in the supply chain, including businesses and consumers, have a role to play. In addition, it is clear that in an EU-wide market cross-border cooperation and coordination with stakeholders is in constant need of strengthening.

4.1. Focus on the supply chain

The development of the single market, the growing number of types of products, the increasing technical complexity of products and the corresponding blurring of boundaries between product categories, pushes the surveillance of the European single market for products towards a system that is more targeted on the different businesses in the supply chain. In addition, the actors in the supply chain change and evolve, and their responsibilities vis-à-vis compliance controls and the safety of their products are often not clearly identified.

Action 14: Improve product traceability

The Commission will speed up its work to improve product traceability in the supply chain. It will evaluate the recommendations of the "Expert Group on Product Traceability" with the objective of improving the quality and availability of traceability information in the supply chain. Up-to-date guidance will be provided by the Commission, after consulting Member States, taking into account the specific needs and interests of SMEs.

Action 15: Compliance scheme operated by Market Surveillance Authorities

The Commission will study the option of developing compliance schemes operated by market surveillance authorities, and integrating them into existing trade-facilitating schemes such as the Authorised Economic Operator.

4.2. Looking further ahead at other categories of products

Within the Union, products are traditionally subdivided into 'consumer' or 'professional', and 'harmonised' or 'non-harmonised' categories. While the safety aspects of a wide range of consumer and professional products are harmonised by European legislation, the safety requirements for consumer products that are not yet harmonised will be further strengthened by the proposal for a Consumer Products Safety Regulation. Yet, a number of 'professional, non-harmonised products' are not subject to European rules on safety or other essential requirements. The absence of rules for these products complicates European market surveillance activities.

Action 16: Professional non-harmonised products - Inquiry on safety issues

The Commission will start an in-depth inquiry into the safety aspects of professional, non-harmonised products, i.e. products that are not subject to European rules on safety or other essential requirements, and the corresponding difficulties for market surveillance authorities.

5. MORE AND BETTER CONTROLS ON PRODUCTS ENTERING THE UNION

Controls of products entering the EU market must be properly implemented, including the possibility to render inoperable or destroy dangerous goods. Controls at borders should be

organised and performed in the same way as within the EU, since checks performed at the first point of entry or during the declaration of goods for release for free circulation prevent the spread of dangerous products on the EU market. The high level of security and safety must be ensured whenever the control takes place.

The control of products manufactured in third countries pose specific enforcement problems due to the immense quantity and diversity of imported goods. They imply the need for a proper cooperation between Customs and the responsible market surveillance authorities of Member States. Customs can target risky consignments and carry out the documentary and physical checks prior to their release for free circulation on the EU market to identify potentially unsafe or non-compliant goods but the final decision on the safety and compliance of goods is to be taken by market surveillance authorities.

5.1. Implementation of the Guidelines for import controls in the area of product safety and compliance and further coordination and cooperation

Controls of products entering the EU market require the involvement of customs authorities, the only service that has a complete overview of trade flows across the EU external borders. In order to provide the necessary knowledge to the authorities and to facilitate the implementation of Regulation (EC) No 765/2008, the Commission, together with the Member States, issued in June 2011 'Guidelines for import controls in the area of product safety and compliance'. The Guidelines are intended as an instrument to assist customs in performing controls on product safety and compliance and to improve cooperation between customs authorities and market surveillance authorities. Actions envisaged include data collection on control results and joint enforcement actions.

Action 17: Support for implementation of the Guidelines in the Member States

The expert team from the Commission and the Member States will complete visits to all Member States in 2015. These visits are intended to facilitate the implementation of the Guidelines by customs and market surveillance authorities. They will also allow customs authorities to have an overview of the market surveillance objectives and organisation at national and EU levels, with specific reference to the treatment of SMEs.

Action 18: Improve the efficiency of border safety and compliance controls

In the context of the Commission's 'Customs 2013 Expert Working Group', continued support will be provided for coordination, shared activities, good cooperation and exchange of information to increase the efficiency of border safety and compliance controls This should ensure better results with fewer resources. It will also contribute to ensuring consistent and efficient implementation and enforcement of EU provisions.

Action 19: Mapping the differences in dealing with safety and compliance controls for products entering the Union

The organisation and technical support for product safety and compliance controls at the points of entry in the Union could vary, amongst others due to the differences in volumes and types of traffic. The Commission will check and map the situation.

5.2. A common risk approach to customs controls in the area of product safety and compliance

Appropriate risk management is a prerequisite for efficient import controls. This has been highlighted in the Communication from the Commission on Customs Risk Management and Security of the Supply Chain[12] which also covers control aspects related to product safety and compliance requirements.

Customs and market surveillance authorities will work more closely in order to develop common risk criteria and specific risk profiles, and will identify where and how to get the information that would enable customs to better target the consignments that pose a safety risk.

Action 20: Development of a common risk approach to customs product safety and compliance controls

The Commission, together with the Member States, will set up a common approach for managing risk at the point of import.

6. CONCLUSION AND NEXT STEPS

As well as setting priorities for the coming three years, the Commission is already considering steps to be taken beyond 2015. The single market and market surveillance should be reoriented and energised to serve the objectives of the Europe 2020 Strategy, which sets out objectives for the next 10 years. Market surveillance contributes to the objectives of protecting health and safety and eliminating unfair competition.

By the end of 2015, the Commission will look into the need to launch a new multi-annual market surveillance plan which could draw inspiration and benefit from the experiences triggered by the implementation of EU programmes for consumers and customs. The Commission will also consult all concerned parties about the next steps to take.

Citizens and businesses will not be able to reap the full benefits of Union rules on industrial and consumer products through the implementation of this multi-annual action plan alone. This set of actions is just the first in a series of efforts being made to strenghten market surveillance in the Union. But this plan is a major step in the right direction for Union market surveillance.

Consequently, the Commission:

- calls upon the European Parliament, the Council and the European Economic and Social Committee to support this plan;
- will work with the Member States and stakeholders to facilitate the swift implementation of the plan;
- calls upon all relevant national authorities including customs and stakeholders to ensure that this plan is implemented on time.

[12] COM(2012)793 final