

## MARKET SURVEILLANCE ACTIVITY IN ROMANIA

In Romania the competent authorities responsible for the performance of market surveillance activities ensure the functioning of an effective and efficient system for the market surveillance of the products covered by “European Union harmonisation legislation”. The competent authorities nominate the market surveillance authorities in the national legislation implementing/transposing the European Union harmonisation legislation. The market surveillance authorities must have the necessary resources and authority to perform their activity, to assure the competence and professional integrity of their employees and to act independently and impartially.

The market surveillance covers Romania’s entire territory.

The market surveillance activity aims to control the following aspects:

- a) if the products covered by European Union legislation harmonising the conditions for the marketing of products, hereinafter named ‘products’, as they are defined in article 15 (4) of the Regulation (CE) no.765/2008, comply with the requirements set out in the European Union legislation or in the national legislation implementing/transposing the European Union legislation harmonising the conditions for the marketing of products, applicable, by case;
- b) if the economic operators, in conformity with their responsibility, act so that the non-conform products will be brought in conformity with the requirements set out in the European Union legislation or in the national legislation implementing/transposing the European Union legislation harmonising the conditions for the marketing of products, applicable, by case, and if they enforce the measures disposed by the market surveillance authorities, where necessary.

In Romania the market surveillance authorities are central administration structures or public institutions, specialised state bodies for specific areas. Entities like those mentioned above which have notified bodies within their structure may not be market surveillance authorities.

For the purpose of performing the tasks under their responsibility, the market surveillance authorities must:

- a) establish, together with all the parties involved, and periodically update, market surveillance programs, as part of the national market surveillance program, covering the sectors in which they conduct market surveillance, taking into account the risks for the health’s protection, for the users’ safety, for the property’s and environment’s protection. They communicate the

market surveillance programs to the Ministry of Economy, Trade and Business Environment, and make them available to the public;

- b) monitor and act for the updating of the scientific and technical knowledge of its employed personnel and of the co-working personnel concerning the products' safety;
- c) draw up half-yearly reports and draw them up whenever necessary, according to the provisions of the European Union legislation or the national legislation implementing/transposing the European Union legislation harmonising the conditions for the marketing of products, regarding the results of the market surveillance activities, presenting them to the competent authority responsible for the regulation of the field in which the market surveillance authorities operates;
- d) revise their procedures, organization and operating conditions whenever necessary, with the purpose of developing an efficient control activity;
- e) ensure the performance of the information exchange and the abidance by the conditions connected thereof;
- f) be in the position to intervene, through their designated representative, in the case of a custom authority notification related the suspension of release from free circulation of one product, and to communicate the decision regarding the actions which has to be undertaken, in the period of time stipulated at the article 28(1) from the Regulation (CE) no. 765/2008;
- g) issue public statements in which they have to specify the products which are or can be insecure, the economic operators who have placed on the market and/or put into function or made available on the market such products, and/or those economic operators whose practices or activities regarding certain products, can negatively affect the users' health and safety, environment protection, domestic animals and proprieties or other interests covered by the European Union legislation or the national legislation transposing/implementing the European Union legislation harmonising the conditions of marketing of products;

The Ministry of Economy, Trade and Business Environment ensures the coordination of the market surveillance activities, in conformity with the applicable requirements established in Regulation (CE) no.765/2008. To this purpose the Ministry of Economy, Trade and Business Environment established the Coordinating Committee regarding the market surveillance of the products covered by "European Union harmonisation legislation". The members of the Coordinating Committee are the designated representatives of competent authorities, of market surveillance authorities, customs authority and national standardisation body. The Coordinating Committee

assures the proper framework for communication and information exchange between competent authorities and market surveillance authorities, between market surveillance authorities and the authority in charge with external borders control, and also between all the market surveillance authorities, in order to guarantee that the products covered by “European Union harmonisation legislation” fulfil requirements which offer a high level of protection of public interests like health and safety in general, health and safety at workplace, consumer protection, environmental protection and security.

The market surveillance authorities and their competence areas are as follows:

1. The National Authority for Management and Regulation in Communications (ANCOM): (1) radio and telecommunications terminal equipment and (2) electromagnetic compatibility;
2. Romanian Naval Authority – Market Surveillance Department: (1) Recreational craft, components, outboard or inboard engines for recreational craft; (2) Life-saving appliances, fire protection, navigation equipment and radio-communication equipment;
3. Labour Inspection: Machinery; Noise outside buildings; Personal protective equipment; ATEX; Civil use explosives; Pyrotechnic articles; low voltage;
4. State Inspection for Construction: construction products except those with a role in meeting fire safety requirements;
5. National Authority for Control of Boilers, Pressure Vessels and Hoisting Equipment – ISCIR: (1) Simple Pressure Vessels; (2) Pressure Equipment; (3) Transportable Pressure Equipment; (4) Gas Appliances; (5) Boiler Efficiency; (6) Lifts; (7) Cableway installations ; (8) Aerosol dispensers;
6. General Inspectorate for Emergency Situations – Construction products with a role in meeting fire safety requirements;
7. Romanian Bureau of Legal Metrology - Inspection and Market Surveillance Department – (1) Non automatic weighing instruments ; (2) Measurement instruments;
8. Ministry of Health – Public Health and Control in Public Health Department: (1) Cosmetic products; (2) Biocide products; (3) Tobacco products;
9. National Authority for Consumers Protection - ANPC: (1) electrical equipment designed for use within certain voltage limits; (2) Electromagnetic compatibility; (3)

Airborne noise emitted by household appliances; (4) safety of toys; (5) Cosmetic products; (6) Detergents; (7) Household electric refrigerators, freezers and combinations thereof; (8) Energy labelling of household lamps; (9) Labelling of the materials used in the main components of footwear; (10) Textile products; (11) General Products Security; (12) Availability of consumer information on fuel economy and CO<sub>2</sub> emissions in respect of the marketing of new passenger cars; (13) Quality of petrol and diesel fuels; (14) Batteries and accumulators and waste batteries and accumulators; (15) Energy labelling of household washing machines; (16) Energy labelling of household combined washer-driers; (17) Waste electrical and electronic equipment ; (18) Ecodesign requirements for standby and off mode electric power consumption of electrical and electronic household and office equipment; (19) Ecodesign requirements for simple set-top boxes; (20) Ecodesign requirements for no-load condition electric power consumption and average active efficiency of external power supplies; (21) Ecodesign requirements for non-directional household lamps; (22) Ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps;

10. Ministry of Health – Medical Device Department: (1 ) medical device; (2) Active implantable medical device; (3) In vitro diagnostic medical devices ;
11. Ministry of Agriculture and Rural Development – State Inspection for roadworthiness wine, production and use vegetables and fruit, organic farming, GMOs and fertilizers, food, livestock, carcass grading, licensing and permit deposits and national seed quality inspection: chemical fertiliser.
12. Ministry of Agriculture and Rural Development - National Phytosanitary Agency: phytosanitary;
13. Romanian Regulatory Authority for Energy – Energy efficiency labeling of household electric appliances and lamps;
14. National Environmental Guard – verifying the provisions of the Regulation no.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.