

Summary

of the National Market Surveillance Strategy of Bulgaria

for the period 2022-2025 (version 2.0 - 2025)

1) General information

The national market surveillance strategy of the Republic of Bulgaria is drawn up in pursuance of the provisions of Article 13 of Regulation (EC) 2019/1020 and covers a 4-year period – from 1 January 2022 to 31 December 2025. The strategy aims at promoting a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of Union harmonisation legislation within the territory of the Republic of Bulgaria, including the borders for which the Republic of Bulgaria is responsible.

The strategy covers the relevant acts of Union harmonisation legislation as described in Annex I of Regulation (EC) 2019/1020.

The information in the strategy has been structured and summarized by the Ministry of Economy and Industry (MEI), Directorate European affairs and EU legislation for goods and services (the former Technical Harmonisation Directorate) in its capacity of a Single Liaison Office (SLO) in accordance with Article 10, paragraph 3 of Regulation (EC) 2019/1020, which will monitor the implementation of the strategy at annual basis through the submission by the individual market surveillance authorities of reports on a calendar year basis.

It is an obligation of the EU Member States according to Article 13 of Regulation (EC) 2019/1020 to draw up a strategy and publish a summary which should be publicly accessible.

The first assessment of the implementation of the strategy will be performed by 16 July 2024 within the framework of the European Union Product Compliance Network (EUPCN) in accordance with Article 31(2)(o) of Regulation (EC) 2019/1020.

2) National infrastructure and organisation of market surveillance

The Republic of Bulgaria follows a decentralised model of market surveillance system, i.e. the country neither has a single authority performing market surveillance functions nor a separate legislative act regulating the way of its performance. The market surveillance functions are entrusted to various institutions by means of a number of legislative acts (specialised sectoral laws) according to the specifics of the product group and obligations of economic operators are introduced. In that respect the Republic of Bulgaria is among those EU Member States that use the approach of organising market surveillance basically at sectoral level. The system of MSAs functions with a strict allocation of competencies among the relevant structures. In certain cases several authorities have shared responsibilities, i.e. several authorities are responsible for the check of different aspects of one and the same product.

Market surveillance authorities are designated within the following 8 structures of public administration: Commission for Consumer Protection (CCP), State Agency for Metrological and Technical Surveillance (SAMTS), Ministry of Environment and Water (MOEW - performing control and methodological functions) through its 15 Regional Inspectorates of Environment and Water (RIEW), Ministry of Health (MH - performing control and methodology functions) through its 28 Regional Health Inspectorates (RHI), Ministry of Agriculture and Food (MAF) via its Department „Control and Technical Inspection“ (CTI), Executive Medicines Agency (EMA), Bulgarian Food Safety Agency (BFSA), Executive Agency Maritime Administration (EAMA). The central offices of the above listed structures are engaged with the control and methodological activities, including the policy making, setting strategic objectives, programming and planning, elaboration of methodological guidelines and monitoring of market

surveillance activities, and the inspectors from the regional structures carry out the pure market surveillance checks.

Such kind of a system presupposes significant coordination. In practice, it is performed by the Single Liaison Office (SLO) that plays the key role of a coordination unit in the communication with the various market surveillance authorities per sectors and the National Customs Agency with a view to ensuring effective implementation of Regulation (EC) 2019/1020. Within the framework of the above mentioned coordination the whole information received via the EUPCN established according to Article 29 of Regulation (EC) 2019/1020 as well as the information received via the Committee on market surveillance established according to Article 43 of Regulation (EC) 2019/1020 is exchanged regularly and in due time.

The described national MSAs perform functions related to the control and surveillance of products according to their competencies carrying out at the same time joints inspections, these including inspections performed by several MSAs as well as joint inspections of MSAs and the National Customs Agency.

The national customs authority – National Customs Agency (NCA) is not a market surveillance authority but it carries out the functions and tasks set out in the Customs Law, the Rules of Procedure of the NCA as well as other tasks entrusted to it by law. In respect of the implementation of the provision of Article 25, paragraph 1 of Regulation (EC) 2019/1020 it has been considered that there are no reasons which necessitate the designation of other authorities except for the customs authorities as authorities responsible for the control of products entering the Union market according to Regulation (EC) 2019/1020, including as authorities responsible for customs control of non-Union goods subject to Union harmonisation.

With a view to increasing the efficiency of the performed activity related to market surveillance and products compliance the active coordination among the various MSAs as well as coordination between the MSAs and the customs authorities is of significant importance. The latter is performed on the basis of agreements concluded between the respective MSAs within the meaning of Article 10, paragraph 2, on the one hand, and the NCA as an authority designated under Article 25, paragraph 1 of Regulation (EC) 2019/1020, on the other hand. The documents signed by the respective MSAs for cooperation with the NCA lay the foundations for the existing cooperation mechanism between these two types of authorities. Pursuant to such agreements the regular cooperation between the national MSAs and the authorities responsible for control of products entering the Union market will be maintained. In such a way the meeting of requirements of Regulation (EC) 2019/1020, aimed to guarantee that finally no unsafe and non-compliant goods enter the Union market, will be ensured.

The market surveillance on the territory of the country is carried out in pursuance of the general objectives for protection of the health of persons, the protection of consumers and other end users, the protection of plants and animals, the protection of the environmental as well as other aspects of the public interest protection with a view of ensuring that economic operators fulfil their legal obligations related to placing on the market of safe and compliant products while ensuring conditions for fair competition. The market surveillance activity aims at contributing to raising awareness of economic operators regarding the legislative requirements and their responsibilities respectively.

Within the framework of the market surveillance system in Bulgaria the strict compliance with legislative requirements is achieved by application of control and surveillance procedures (such as prevention, documentary and physical checks, withdrawal, recall, etc.) and relevant methods with a view of avoiding marketing of dangerous and non-compliant products.

With respect to prevention activities the MSAs carry out active policy for awareness raising of businesses and the society. The most frequent topics for discussions and clarification are related to the requirements of the European legislative framework regarding the safety of goods and the conformity assessment procedures.

Within the framework of prevention activities the MSAs carry out active information awareness policy targeted at businesses and society. Most often the requirements of European legislative framework regarding product safety and conformity assessment procedures are put as topics for discussion. As part of prevention activities the MSAs provide relevant information on their websites and often develop Questions and Answers sections, „advice to consumers”, etc.; carry out information campaigns; participate in various fora and workshops.

The information exchange among authorities is a key prerequisite for the effectiveness of the market surveillance activity. Within the framework of their control activity the MSAs use the information received within the EU Rapid Alert System for Dangerous Non-Food Products - Safety Gate/RAPEX, or via the information and communication system for market surveillance (ICSMS), or as a result of cooperation with the competent authorities of other Member States or with the mirror structures of the European Commission.

The national contact point for the Safety Gate/RAPEX is the Commission for Consumer Protection. The SLO in the Ministry of Economy and Industry performs the functions of a national ICSMS administrator. As regards EUDAMED - access to it is provided only for the experts of EMA as a competent authority.

3) Background information

The market surveillance activity in Bulgaria is performed in compliance with the provisions of Regulation (EU) 2019/1020. The MSAs carry out checks through the whole supply chain with a view to identifying the first operator that has placed the products on the market.

- **Approaches**

The national MSAs apply different approaches with regard to market surveillance that vary according to the specifics of the respective product sector. However, generally the market surveillance activities are performed by applying the so called proactive and reactive approach.

In the case of the proactive approach a preliminary planning of the checks is done by taking into consideration a number of factors among which an analysis of the results of the checks carried out during the previous periods, signals and complaints received by consumers, information by other control authorities, notifications through Safety Gate/RAPEX and ICSMS, publications in the media, etc. When applying that approach various campaign checks under different logos are organised, such as Safe Christmas, Safe Summer, campaigns for the Children's day, etc.

The reactive approach is performed by carrying out immediate checks on the basis of received notifications through the Safety Gate/RAPEX or through the ICSMS, notifications by the NCA, information by media, consumer complaints and signals.

- **Procedures**

The respective MSAs have developed and apply its own procedures, including dealing with complaints, ensuring a common approach in the performance of their surveillance activities and thus complying with the requirements of Article 11 of Regulation (EC) 2019/1020.

- **Principles**

In carrying out its activities the national MSAs are led by the following basic principles:

- Proportionality – the authorities should undertake appropriate and proportionate measures, including in the case where the economic operator does not take appropriate corrective action. In that respect the sanctions imposed need to be proportionate to the level of infringement established. National provisions on sanctions are included in the respective specialised sectoral laws.
- Openness and transparency – the opinion of the business is actively looked for when developing positions on European acts and the drafts of national legislative acts are

publicly available for comments and positions. The competent authorities regularly publish up-to-date information about the new legislative requirements and forthcoming changes.

- *Awareness raising* – all ways and possibilities are sought for targeted awareness raising activities for the businesses and consumers, including through organization of topical information campaigns.
- *Prioritisation* – the whole allocation of activities is led by the effective protection of the interests of consumers and other aspects of public interest protection where the respective MSAs are responsible for the sectoral prioritization of market surveillance activities within their competencies.
- *Cooperation* – all ways of active cooperation are being sought for both at national and EU level.

- ***System of penalties***

All specific laws of the national legislation of the Republic of Bulgaria which regulate the market surveillance activity of the MSAs listed in Annex contain administrative and penal provisions. They provide for imposing fines, property sanctions and compulsory administrative measures in respect of persons that have performed administrative offences. The main kind of administrative punishment provided for in the Bulgarian legislation is the fine which in respect of legal persons and natural persons is called “a property sanction”. The general regulation of the fine related process is the Law for the administrative offences and sanctions. Usually the fine or property sanction provided for in the legislative acts for a specific kind of offence is set as a sum varying from a minimum to maximum amount within the range of which the authority imposing the fine sets its amount.

A significant volume of market surveillance activity is performed, the results of which show a major number of non-conforming products.

The national MSAs strictly follow the market trends. For the purposes of monitoring and focusing the performed market surveillance activity the national MSAs receive information and gather data mainly through:

- Their participation in the AdCos;
- Received signals and complaints;
- The physical checks performed in the trade places and online checks;
- Advertising campaigns, etc.;
- The information received by the National Customs Agency.

Currently the MSAs within the EU are facing great challenges because of the constantly changing environment in which they operate daily. The introduction of new technologies and the more massive introduction of new products and categories of products is one such serious challenge for the MSAs. The latter presupposes not only enhanced exchange of information and practices among the MSAs during the next four years, this including seeking possibilities for training in that respect but also seeking ways for acquiring new knowledge through active cooperation with the academic society and specialised research institutions, but also adapting the market surveillance practices.

4) Strategic choices

Within the planned period 2022-2025 the efforts of the MSAs at national level will be focused on the following horizontal areas:

- Continuing the performance of a proactive and reactive market surveillance through visual and documentary checks of products covered by the acts listed in Annex I of Regulation (EC) 2019/1020;
- Priority activities with regard to control on compliance with legislative requirements;

- Effective participation in ICSMS and Safety Gate/RAPEX;
- Strengthening the regular cooperation with the National Customs Agency with respect to products imported from third countries and enhanced customs control;
- Seeking for efficient forms of cooperation among authorities including through active participation in AdCos as forums for broad practical discussions and reactions on current and new issues, gathering the views of different stakeholders.
- Looking for opportunities for active participation in joint actions financed by the EC.

The participation in AdCos and joint actions financed by the EC have proved to be well working formulas for developing common market surveillance culture and practice, elaboration of common guidelines and procedures as well as harmonised criteria for risk assessment. In fact AdCos are the fora for obtaining up-to-date information on specific sectoral issues where especially useful for the MSAs would be the most frequent cross-sectoral exchange of information between groups sharing similar viewpoints and issues.

Within their market surveillance activities the MSAs use the risk-based approach, whereby the sector priorities for each of the respective MSAs is set out taking into consideration also the specific risks identified.

The priorities set out in the general market surveillance framework at the EU level – the tasks of the EUPCN Working Programme - will also be complied with when carrying out their market surveillance activities during the planned period. In that regard the trends in respect of products sold online will be followed.

As regards the aspect of enforcement of the Union harmonisation legislation listed in Annex I of Regulation (EU) 2019/1020, the existing structure of national MSAs will perform activities in the following priority areas:

- market surveillance mainly on products covered by the acts of the so called New Legislative Framework (*NLF*), which present highest risk or surveillance focused at activities which are expected to have great impact on the general level of safety or compliance of certain products or product categories;
- permanent control in the product sector „Consumer products under GPSD“, control based on the annual subject planning for the respective product groups in the sectors „Energy labelling“, „Textile and Footwear Labelling“ and „Tobacco and related products“;
- systematic control of the implementation of the requirements of Regulation (EC) 1907/2006 (REACH), control on the application of Regulation (EC) № 1272/2008 (CLP), control on the application of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs) and on the application of Regulation (EU) 2017/852 on mercury;
- control for compliance with the requirements of Regulation (EC) No. 517/2014 and Regulation (EC) No. 1005/2009;
- control for compliance with the requirements of the legislation on paints, varnishes and vehicle refinishing products;
- control of products and goods relevant for the health of the population, as well as control of products and goods for public use;
- market surveillance of medical devices that are in the high-risk classes and that have a high impact on the overall level of safety.

The priority areas per respective product sectors are identified by the use of an approach based on the risk analysis, as well as on the basis of a previous experience (including established non-compliances, signals from citizens and other control authorities, RAPEX/Safety Gate and ICSMS notifications) as well as by taking into consideration various factors and arguments related to the specifics of market surveillance per sectors.

5) Implementation plan of the strategy

Within the planned 4-year period the MSAs will regularly carry out their market surveillance activities within the scope of their competences with a view to preventing the access to the market of a more and more non-conforming products. The specific enforcement activities will be performed on the basis of annual plans prepared by the respective MSAs. They will include not only checks on their own initiative but also checks as a result of signals and complaints. The joint activities with the National Customs Agency in its capacity of an authority under Article 25, paragraph 1 of Regulation (EU) 2019/1020 will continue to be performed on the basis of agreements concluded between the NCA and the respective MSAs.

To reduce and prevent the distribution of non-conforming products in the different product groups, different levels of control (low, medium and high) depending on each separate case and also on the grounds of the risk assessment for the product group are envisaged.

6) Cooperation with other Member States

The cooperation among the EU Member States is of significant importance for the national MSAs as it contributes to establishing a more uniform market surveillance practice, achievement of a common understanding on new and conflicting issues, exchange of useful practical experience (including through exchange of officials), and last but not least the promotion of joint inspections and testing. All of the above lays the basis for the strengthening of the EU internal market and is a precondition for a uniform level of protection of consumers, in such a way that the consumers can finally make use of safe and compliant products.

In the field of market surveillance the cooperation among the EU Member States will continue to be performed at several levels and in various forms:

At EU level:

- Within the framework of Union Product Compliance Network (EUPCN) established according to Article 29 of Regulation (EC) 2019/1020;
- Within the respective Commission Working Groups established under relevant sectoral acts, and predominantly within the meetings of AdCos, the Medical Devices Coordination Group (MDCG) and the European Chemicals Agency Forum (ECHA Forum), where serious attention will be paid to seeking maximum opportunities for participation in programmes for exchange of officials and joint visits as well as their financing;
- Within the participation of the MSAs in the EU Rapid Alert System for dangerous non-food products – Safety Gate/RAPEX;
- Within the participation of the MSAs in the Information and Communication System (ICSMS) under Article 34 of Regulation (EC) 2019/1020;
- Within the participation in different cross-border projects, in multinational projects of the Commission related to market surveillance joint actions;
- Within the participation in other formats including activities related to communication with the Commission specialised agencies such as the European Chemicals Agency (ECHA), European Medicines Agency (EMA), European Maritime Agency (EMSA), as well as within the framework of bilateral projects and/or agreements;

At national level:

- Within the participation of several authorities in joint inspections at national level.