REPUBLIC OF MACEDONIA
MINISTRY OF ECONOMY

Law on Market Surveillance
Regulation 765/2008/EC

I. GENERAL PROVISIONS
Subject

Article 1

This Law regulated organization, operation and coordination of market surveillance of products that are placed on the market, control of products that are made available on the market, and enforcement of general principles of CE marking.

Scope

Article 2

The aim of this Law together with specific regulations is to provide coordination of market surveillance of products to ensure that those products fulfil the prescribed requirements providing a high level of protection of public health and safety in general, health and safety at the working place, the protection of consumers, protection of the environment and safety.

Application
Article 3

1) The provisions of this Law apply, in cases when in other laws and regulations adopted according to those laws as harmonised EU legislation, there are no specific provisions with the same objective, nature or have same effect.
2) The provisions of this Law apply to products covered by the Law on Products Safety and the regulations enacted on the basis of that Law and articles 5 to 15 of this Law. (Article 15, paragraph 1 of 765/2008)
3) This Law provides a framework for control on products from third countries.
4) The application of this Law shall not prevent market surveillance organs from taking more specific measures as provided for in the Law on product safety. (Article 15, paragraph 4 of 765/2008)
5) Articles 16, 17 and 18 of this Law shall apply to all products covered by the national legislation as harmonised EU legislation, and in so far other legislation that does not contain specific provisions relating to the organisation of border controls. (Article 15, paragraph 5 of 765/2008)

Terms in use
Article 4

(1) Certain terms applied in this Law have the following meaning:

a) **"making available on the market"** shall mean any supply of a product for distribution, consumption or use on the market of the Republic of Macedonia or on the EU market in the course of a commercial activity whether in return for payment or free of charge;

b) **„placing on the market"** shall mean the first making available of a product on the market in the Republic of Macedonia or on the EU market;

c) **"manufacturer,,** shall mean any legal or natural person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

d) **"authorized representative "** shall mean any legal or natural person established in the Republic of Macedonia or within the EU who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations according to the law and regulations enacted pursuant to that law.

e**) "Importer"** shall mean any legal or natural person established in the Republic of Macedonia or within the EU who places a product from a third country on the market of the Republic of Macedonia or on the Community market.

f) **"Distributor"** shall mean any legal or natural person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

g) **„economic operators"** shall mean the manufacturer, the authorized representative, the importer and the distributor;

m) **"Customs organ"** shall mean an authority in charge of external border controls as prescribed by the Customs Law.

h) **"Recall"** shall mean any measure aimed at achieving the return of a product that has already been made available to the end user.

l) **"withdrawal"** shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

j) **„market surveillance"** shall mean the activities carried out and measures taken by the state organs to ensure that products comply with the requirements set out in the laws and regulations and do not endanger health, safety or any other aspect of public interest protection;

k) **„market surveillance organs"** shall mean state organs responsible for carrying out market surveillance, such as: State Market Inspectorate, State Sanitary and Health Inspectorate, State Labour Inspectorate, State Inspectorate for Technical Inspection, State Environment Inspectorate, Agency for Electronic Communications, Inspection of Transport and Communication and other inspection organs pursuant to the relevant law.

m) **"Release for free circulation"** shall mean the procedure pursuant to the provisions of the Law on Customs.

n) **,,CE marking,,** shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in EU harmonisation legislation or in national laws or regulations transposing EU harmonisation legislation providing for its affixing;

o) ,,Community harmonisation legislation,, shall mean any EU legislation harmonised in national legislation, as harmonising the conditions for the marketing of products.

p) ,,Product,, shall mean a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plans and animals relating directly to their future reproduction. (Article 15, paragraph 4 of 765/2008)

General requirements for market surveillance

Article 5

(1) Market surveillance shall ensure that products covered by EU harmonisation legislation as national legislation, which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not confirm to applicable requirements set out in the laws and the provisions according to those laws, are withdrawn or their being made available on the market is prohibited or restricted and that the public and the competent state organs in the Republic of Macedonia and the Member States of the European Union are informed accordingly.

(2) The organs for market surveillance, in the framework of its annual programs for market

surveillance and the National Program for coordination and providing an effective measures for market surveillance, shall ensure to take measures in relation to any product category according to the national Law as transposing EU harmonisation legislation.

(3) Market surveillance shall also cover products assembled or manufactured for the manufacturer's own use where EU harmonisation legislation as national legislation provides that its provisions shall apply to such products.

(4) Ministry of economy-State Market Inspectorate shall organise and carry out market surveillance for in this Law. (Article 16, paragraph 1 of 765/2008).

II. ORGANISATION, OPERATION AND COORDINATION OF MARKET SURVEILLANCE

Information obligations

Article 6

The Ministry of Economy shall inform the European Commission of the market surveillance organs of the Republic of Macedonia and their areas of competence.

The Ministry of Economy shall ensure that the public is aware of the existence, responsibilities and identity of national market surveillance organs, and of how those organs may be contacted. (Article 17, paragraph 2 of 765/2008).

Coordinative body for market surveillance

Article 7

(1) With aim to establish efficient coordination and communication of market surveillance activities and exchange of data and information, a Coordinative Body for Market Surveillance is established (hereinafter: Coordinative Body).

(2) The Coordinative Body is consisted of a coordinator, deputy coordinator, secretary and representatives of market surveillance organs.

(3) The Coordinative body has 12 members from market surveillance organs.

(4) The coordinator, deputy coordinator and the representatives referred to in paragraph (2) of this Article, are appointed and dismissed by the Government of the Republic of Macedonia at the proposal of the Minister of Economy for period of four years.

(5) The administrative and technical work of the Coordinative Body is performed by the State Market Inspectorate.

Work of the Coordinative Body

Article 8

(1) (1)The Coordinative body shall:

1) establish adequate mechanisms for communication and coordination between the market surveillance organs;

2) establish adequate procedures to:

-follow up complaints or reports on issues relating to risks arising in connection with products that are subject to EU harmonisation legislation as national legislation;

-monitor accidents and harm to health which are suspected to have been caused by those products;

-verify that corrective actions has been taken and that the market surveillance organs are informed on time; and

-follow up scientific and technical knowledge concerning safety issues

3) do activities related to facilitating information and exchange of data between market surveillance organs;

4) provides coordination in implementation of mutual plans and procedures for acting upon urgent cases;

5) prepares and proposes National Program for Coordination and Taking Effective Measures of market surveillance.

(2) The Coordinative Body enacts Rules of procedure for its work.

(3) The Coordinative Body submits to the Government of the Republic of Macedonia a Report at the end of February at the latest of its work in the previous year.

(4) The Report of paragraph 4 of this Article is published on the web site of the Ministry of Economy.

6) The Government of the Republic of Macedonia shall entrust that market surveillance organs with the powers, resources and knowledge necessary for the proper performances of their tasks. (Article 18, paragraph 3 of 765/2008).

National Program for coordination and taking effective measures for market surveillance

Article 9

(1) The National Program for coordination and taking effective measures for market surveillance is adopted by the Government of the Republic of Macedonia for a period of two years.
(2) The National Program for coordination and taking effective measures for market surveillance shall be published on the web site of the Ministry of Economy.
(3) The Ministry of Economy informs the European Commission of the adopted National Program for coordination and taking effective measures for market surveillance, as well for providing the activities set out in the Program.

Obligations of the market surveillance organs
Article 10

(1) The market surveillance organs shall exercise their powers in accordance with the principal of proportionality.

(2) The market surveillance organs shall prepare and adopt their annual programs defining the sector specific programmes in line with the National Program for Coordination and Taking Effective Measures of Market Surveillance, as well to implement the activities of those programs during the year.

(3) The market surveillance organs shall make, implement and periodically updates their annual market surveillance programs and communicate those programs or the National Program for coordination and taking effective measures with Member States and published them on their web site.

(4) Subsequent updates of the programmes or the National program shall be made public in the same manner. (Article 18, paragraph 5 of 765/2008).

(5) Market surveillance organs may cooperate with all relevant stakeholders to those ends. (Article 18, paragraph 5 of 765/2008).

(6) State market surveillance organs shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessment shall be carried out at least every fourth year and the results thereof shall be communicated between Republic of Macedonia, Member States and the Commission and be made available to the public, on the web site and, where appropriate, by other means. (Article 18, paragraph 6 of 765/2008).

Market surveillance measures
Article 11

(1) Market surveillance organs shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.

(2) In case of Paragraph 1 of this Article, market surveillance organs shall take account of established principles of risk assessment, complaints and other information.

(3) Market surveillance organs may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. Market surveillance organs may destroy or otherwise render inoperable the products presenting a serious risk where they deem it necessary.

(4) Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance organs shall take due account of such reports or certificates.

(5) Market surveillance organs shall take appropriate measures to alert users within an adequate timeframe according to the law, of hazards they have identified relating to any product so as to reduce the risk of injury or other damage.

(6) Market surveillance organs shall cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those economic operators.

(7) In case when market surveillance organs decide to withdraw a product manufactured in an EU Member State, they shall inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying that product.

(8) Market surveillance organs shall carry out their duties independently, impartially and without bias.

(9) Market surveillance organs shall observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to the legislation on personal data and the approach to classified information, subject to the requirement that information be made public to the fullest extent necessary in order to protect the interests of users in the Republic of Macedonia and in the EU.

(10) Physical and laboratory testing of representative samples according to paragraph 1 of this Article shall be determined in schedule prescribed in the National program for coordination and taking an effective measures for market surveillance, and the assets necessary for testing or checking shall be within the budget amount and the financial plans of market surveillance organs.

Products presenting a serious risk
Article 12

(1) Market surveillance organs shall ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on the market is prohibited.

(2) In cases referred to in paragraph (1) of this Article, the State Market Inspectorate shall inform immediately, and without delay, the European Commission through the Community Rapid Information System (RAPEX) in accordance with Article 14.

(3) 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. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

Restrictive measures

Article 13

(1)Market surveillance organs shall ensure that any measure taken, pursuant to the relevant EU harmonisation legislation as national laws or regulations transposing EU harmonisation legislation, to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.

(2)For measures of paragraph 1 of this Article shall be communicated without delay to the relevant economic operator, which shall at the same time be informed of the remedies available under the law and of the time limits to which such remedies are subject.

(3)Prior to the adoption of a measure referred to in paragraph (1) of this Article, the economic operator concerned shall be given the opportunity to be heard within a period of not less than 10 days from the day when the economic operator received a report of provided surveillance.

(4) With exception of paragraph 3 of this Article, unless such consultation with the economic operation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by the relevant EU harmonisation legislation as national laws.

(5) In case of paragraph 4 of this Article, an action has been taken without the operator's being heard, then the operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter.

(6) Any measure referred to in paragraph 1 shall be promptly withdrawn or amended upon the economic operator's demonstrating that he has taken effective action.

Exchange of information through the Rapid Information System on products that present serious risks (RAPEX)

Article 14

(1)Where a market surveillance organ takes or intents to take measure in accordance with Article 12 of this Law and considers that the reasons which prompted the measure or the effects of the measure go beyond the territory of the Republic of Macedonia, the Ministry of Economy-State Market Inspectorate shall immediately notify the European Commission of that measure, in accordance with paragraph 4 of this Law, the Law on Product Safety and the by-law on RAPEX. It shall also inform the European Commission without delay of the modification or withdrawal of any such measures.

(2)If a product presenting a serious risk has been made available on the market, the State Market Inspectorate shall notify the European Commission of any voluntary measures taken and communicated by an economic operator.

(3)The information provided in accordance with paragraphs (1) and (2) of this Article shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

(4) For the purposes of paragraph 1, 2 and 3, the market surveillance and information exchange system provided for in Article 18 of the Law on product safety shall apply mutatis mutandis.

(5) Ministry of economy-State market surveillance and Member States shall provide the Commission with information at their disposal and not already provided in Paragraphs 1, 2, 3 and 4 of this Article on products presenting a risk regarding, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction. (Article 23 paragraph 2 of Reg. 765/2008)

Principles of cooperation between the Republic of Macedonia, Member States and European Commission

Article 15

(1) Market surveillance organs shall ensure efficient cooperation and exchange of information between themselves and the market surveillance authorities of the EU Member States, the European Commission and the relevant Community agencies regarding their market surveillance programs and all issues relating to products presenting risks.

(2) For the purposes of paragraph (1) of this Article, the market surveillance organs shall give assistance to the market surveillance authorities of any EU Member State on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other measure and by participating in investigations initiated in EU Member States.

(3) Any information provided by an economic operator under paragraph (3) of Article 13 of this Law or otherwise shall be included when the reporting market surveillance organ notifies the EU Member States and the European Commission of its findings and actions. Any subsequent information by the market surveillance organ shall be clearly identified as relating to the information already provided.

Republic of Macedonia and EU market

General requests for control of products entering the market of the Republic of Macedonia or the EU market

Article 16

(1) The customs organ, in cooperation with market surveillance organs, is in charge of the control of products entering the market, within their competencies and resources necessary for the proper performances of their tasks, according to the laws.

(2) Organs mentioned in Paragraph 1 of this Article, shall carry out appropriate checks on the characteristics of the products on an adequate scale, in accordance with the principles set out in paragraphs (1), (2) and (3) and (4) of Article 11 of this law, before those products are released for free circulation.

(3) The customs organ and market surveillance organs shall cooperate with each other by sharing information relevant to their function and otherwise as appropriate.

(4) The customs organ shall suspend release of a product for free circulation when any of the following findings are made in the course of the checks referred to in paragraphs (1) and (2) of this Article:

a) The product displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, environment or any other public interest referred to in Article 2.

b) The product is not accompanied by the written or electronic documentation required by the relevant EU harmonisation legislation as national laws or regulations transposing such EU harmonisation legislation or is not marked in accordance with that legislation.

c) The CE marking has been affixed to the products in a false or misleading manner.

(5) In cases of paragraph (4) of this Article, the customs organ shall immediately notify the market surveillance organs of any such suspension.

(6) In the case of perishable products, customs organ controls shall, as far as possible, seek to ensure that any requirements they may impose with regard to the storage of products or the parking of vehicle used for transport are not incompatible with the preservation of those products.

(7) For the purpose of efficient providing of the goals of this article, the customs organ and the market surveillance organs shall conclude memorandum of cooperation.

(8) For the purpose of this Section, Article 15 shall apply in respect of customs organ without prejudice to the application of EU legislation as national laws providing for more specific systems of cooperation between market surveillance organs and itself.

Release of products into circulation

Article 17

(1) A product the release (into circulation) of which has been suspended by the customs organ pursuant to article 16 of this law, shall be released if, within three working days of the suspension of release, the customs organ has not been notified of any action taken by the market surveillance organs, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

(2) Where the market surveillance organs find that the product in question does not present a serious risk to health and safety or cannot be regarded as being in breach of EU harmonisation legislation as national laws or regulations transposing EU harmonisation legislation, that product shall be released, provided that all the other requirements and formalities pertaining to such release have been fulfilled.

National measures

Article 18

(1) Where the market surveillance organs find that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the customs organs to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

"Dangerous product - release for free circulation not authorised –provisions of relevant laws regulating the Regulation (EC) 765/2008" are prescribed.

(2) Where the market surveillance organs find that a product does not comply with EU harmonisation legislation as national laws or regulations transposing EU harmonisation legislation, they shall take appropriate action, which may, if necessary, include prohibiting the product's being placed on the market.

(3) Where placing on the market is prohibited pursuant to paragraph (2) of this Article, the market surveillance organs shall require the customs organs not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

"Product not in conformity - release for free circulation not authorised - provisions of relevant laws regulating the Regulation (EC) 765/2008" are prescribed.

(4) Where that product is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance organs do not object, the endorsements set out in paragraphs (1) and (3) of this Article shall also be included, under the same conditions, on the documents used in connection with that procedure.

(5) The market surveillance organs in cooperation with the customs organs may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary and proportionate.

(6) Market surveillance organs shall provide the customs organs with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs (1), (2) and (3) of this Article has been identified.

IV. CE MARKING

Affixing of CE marking

Article 19

The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant EU harmonisation legislation as national laws or regulations transposing such EU legislation providing for its affixing.

MK NOTE: Macedonian products when entering on EU internal market or European products entering our domestic market, the CE marking is there. CE marking is widely in use in our mutual trade. Only notified bodies are in charge of this marking. Our authorised bodies are not included in the marking process, unless notified body is willing an authorise body to do the examination for him. Certificate of conformity is recognized in the rulebooks within the Law on product safety, as a temporary national conformity marking. In that respect, we shall not give any postponing of this Article.

General principles of the CE marking

Article 20

1. The CE marking shall be affixed only by the manufacturer or his authorized representative.
2. The CE marking as presented in the by-laws as regulating New Approach directives, as being part of the Law on products safety.
3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant EU harmonisation legislation as national laws or regulations transposing such EU legislation providing for its affixing.
4. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be fixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.
5. The economic operators shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking.
6. State market inspection organs shall provide for penalties for infringement, which may include criminal sanction for serious infringements according to the relevant domestic laws regulating penalties sanctions and the Law on criminal code. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

V. TRANSITIONAL AND FINAL PROVISIONS

Regulations
Article 21

Market surveillance organs are obliged to adjust their annual working programs with the provisions of this law in term of six months from the day of entering into force of this Law.

Article 22

(1) Coordinator, deputy coordinator, secretary and representatives of market surveillance organs shall be appointed by the Government of the Republic of Macedonia in time of 60 days from the day of entering into force of this Law.
(2) The National program for Coordination and Taking an Effective Measures shall be prepared in time of six months from the day of entering into force of this law.
(3) The Memorandum of cooperation from paragraph (6) of Article 16 of this law shall be concluded in time of six months from the day of entering into force of this Law.

Article 23

The provisions of Article 11 paragraph (7), 12 paragraph (2), Article 14 paragraph (1) and Aricle 15 of this Law shall be applicable from the date of entering into force of an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with the EU.

Article 24

This Law shall be ceased from the date of accession of the Republic of Macedonia in EU.

Article 25

This law enters into force on the eight day from the date of its publication in the “Official Gazette of Republic of Macedonia”.