

## FREE MOVEMENT OF GOODS

I. HORIZONTAL LEGISLATION AND IMPLEMENTING INFRASTRUCTURE .....	2
A. LEGAL BASIS AND ADMINISTRATION .....	2
B. REGULATION/ADMINISTRATIVE CAPACITY .....	11
C. STANDARDISATION.....	11
D. ACCREDITATION .....	14
E. CERTIFICATION / TESTING / INSPECTION.....	16
F. METROLOGY .....	17
G. MARKET SURVEILLANCE .....	19
H. INTERNATIONAL AGREEMENTS.....	20
II. SECTOR SPECIFIC LEGISLATION .....	21
A. COMPETENT AUTHORITY/IES .....	21
B. CALIBRATION, METROLOGY, STANDARDS, TESTING, CERTIFICATION, CONFORMITY ASSESSMENT, ACCREDITATION AND MARKET SURVEILLANCE .....	29
III. FOOD LEGISLATION.....	31
A. COMPETENT AUTHORITY/IES .....	31
B. LEGISLATIVE POWERS FOR FOOD LEGISLATION .....	43
C. CONTROL ACTIVITIES AND ENFORCEMENT IN THE FIELD OF FOOD LEGISLATION .....	45
D. TRANSPOSITION AND IMPLEMENTATION OF LEGISLATION .....	47
<i>Preparation of administration and operators:</i> .....	54
IV. NON-HARMONISED AREAS .....	65
A. MEASURES HAVING AN EQUIVALENT EFFECT TO QUANTITATIVE RESTRICTIONS.....	65
B. RETURN OF UNLAWFULLY REMOVED CULTURAL OBJECTS .....	76
C. CONTROL OF THE ACQUISITION AND POSSESSION OF WEAPONS.....	82
D. CHECKS FOR CONFORMITY WITH THE RULES ON PRODUCT SAFETY IN THE CASE OF PRODUCTS IMPORTED FROM THIRD COUNTRIES .....	88
V. PUBLIC PROCUREMENT .....	90
A. STATE OF LEGISLATION IN THE FIELD OF PUBLIC PROCUREMENT .....	90
B. STRUCTURES.....	95
C. PUBLICATION.....	98
D. LEGAL FRAMEWORK.....	99

## I. HORIZONTAL LEGISLATION AND IMPLEMENTING INFRASTRUCTURE

### *A. Legal basis and administration*

#### **1. What is the legal basis and administrative structure for technical regulations, standards, conformity assessment, accreditation, certification, metrology and market surveillance?**

The framework of the activities that the Republic of Macedonia must undertake to meet the commitments arising from the Stabilisation and Association Agreement was established in accordance with the National Programme on Quality, adopted by the Government of the Republic of Macedonia in 2001.

Among other activities, a priority for the 2001-2003 period was the establishment of a legal framework for technical regulations, standards, conformity assessment, accreditation, certification, metrology and market surveillance.

The projected activities have been carried out and the following laws are the current legal basis that regulate the administrative structure:

- The Law on Standardisation (“Official Gazette of RM” No. 54/2002)
- The Metrology Law (“Official Gazette of RM” No. 55/2002)
- The Law on Accreditation (“Official Gazette of RM” No. 54/2002)
- The Law on Prescribing Technical Requirements for Products and Conformity Assessment (“Official Gazette of RM” No. 55/2002)
- The Law on Market Inspection (“Official Gazette of RM” No. 35/97, 23/99, 7/2002)
- The Trade Law (“Official Gazette of RM” No. 16/2004)
- The Consumer Protection Law (“Official Gazette of RM” No. 38/2004)

The abovementioned Laws are in conformity with European legislation.

- The Law on the Quality Control of Agricultural and Food Products in Foreign Trade Circulation (“Official Gazette of RM” No. 5/98)

#### **The Law on Standardisation**

This Law regulates the objectives and principles of Macedonian national standardisation, the status of the Institute for Standardisation of the Republic of Macedonia (ISRM), as well as its tasks, membership and funding, preparation, adoption and publication of Macedonian national standards and their application.

The primary objectives of Macedonian national standardisation consist of improving:

- product quality, the procedures and services by defining their features which determine their capacity to satisfy certain requirements;
- the quality of life and people’s health, property safety, and environmental and nature protection;
- the cost-effectiveness and rationality in using manpower, materials and energy in the process of production and exchange of goods;
- Industrial efficiency by reducing and harmonising the variety of certain products, processes and services, as well as the possibility to replace a product, process or service with another meeting the same requirements; and
- international trading in goods and services by removing obstacles to trade.

Macedonian national standardisation is based on the following principles:

- voluntary application of Macedonian standards;

- the right of all stakeholders to take part in the development of Macedonian standards, protection from domination of individual over common interests in the Macedonian standard development procedure;
- consensus of all stakeholders regarding the contents of Macedonian standards;
- transparency of the development procedure for Macedonian standards;
- compulsory publication of the adoption of Macedonian standards; and
- compliance with the scientific and technical degree of development and experience, as well as compliance with the rules of international and European standardisation.

### **The Metrology Law**

This Law regulates the metrology system in the Republic of Macedonia; the competence of the Bureau of Metrology; legal units of measurement; standards; reference materials, circulation and use of measurements; conformity assessment for the type of measurement; verification of measurements; validity of markings and certificates for conformity of the type of measurements and the marks and brands, i.e. the certificates for verifying foreign measurements; metrological supervision of the quantities and markings of packed products; supervision of the implementation of this Law and other issues important for the metrology system in order to provide measurement unification in the Republic of Macedonia.

The provisions of this Law relate to the measurements used to ensure:

- protection of the health of humans, animals and plants;
- environmental and nature protection;
- general technical safety;
- free trade of goods and services; and
- procedure before administrative and judicial authorities.

### **The Law on Accreditation**

This Law regulates the establishment, setup and operation of the Macedonian Institute for Accreditation as a public institution carrying out the work and tasks of a national accreditation service, as well as the accreditation procedure carried out in accordance with this and other laws and regulations adopted on the basis of law and supervision of meeting accreditation requirements.

The Institute for Accreditation of the Republic of Macedonia (IARM) primarily issues accreditation to:

- testing and calibration laboratories;
- product certification authorities;
- quality systems certification authorities;
- authorities certifying environmental and nature protection systems;
- person certification authorities; and
- inspection (control) authorities.

The Institute for Accreditation of the Republic of Macedonia carries out the accreditation procedure on the basis of this Law and other laws and in conformity with the requirements contained in the relevant national, European and international standards and documents of European and international accreditation organisations.

Accreditation is a public interest activity.

### **The Law on Prescribing Technical Requirements for Products and Conformity Assessment**

This Law regulates:

- the technical requirements that products must comply with;
- the manner of releasing in circulation;
- the procedure for conformity assessment (testing, certification and inspection control);
- Requirements that authorities taking part in the conformity assessment procedure must meet;
- the documents accompanying the product when released in circulation;
- the authority in charge of supervising the product market;

- the method of and obligation for product marking.

Technical requirements primarily concern:

- the exercise and protection of public interest;
- the protection of the life and health of humans, animals and plants;
- protection and improvement of the environment; and
- nature and protection of consumers and other product users.

### **The Law on Market Inspection**

This Law regulates the competencies, authorisations and organisation of the State Market Inspectorate.

### **The Trade Law**

The Trade Law regulates trading both on the domestic and on the foreign market, enabling unhindered trading and establishment of mutual trust and cooperation among WTO members which, in turn, will contribute to reducing trade barriers and provide an equal treatment of trading subjects on the market.

This Law regulates the conditions for carrying out wholesale and retail operations, sales on wholesale and retail markets, trade services etc.

The Trade Law is the only law regulating trading both on the domestic and on the foreign market, enabling unhindered trading by establishing mutual trust and cooperation among WTO members which, in turn, will contribute to reducing trade barriers and provide an equal treatment of trading subjects on the market.

Trade will stimulate economic development, opening markets, a larger selection of products, as well as establishing greater safety and discipline in the circulation of goods and provision of services in this field.

The Trade Law succinctly provides for the obligations of traders for a market approach, as well as for strengthening the authorisations and competencies of the inspection authorities in its enforcement.

In accordance with the Trade Law, the trader is obliged to report the satisfaction of the minimum technical requirements and the commencement of operations to the State Market Inspectorate and to the competent municipal authority, i.e. the city of Skopje, at least 15 days prior to the commencement of operations of the sales or other business premises.

The procedure for establishing the minimum technical requirements for carrying out a certain activity is simplified with the adoption of the Law.

In accordance with the Law, the trader is obliged to report the satisfaction of the requirements to the State Market Inspectorate and to the competent municipal authority, i.e. the city of Skopje, at least 15 days prior to the commencement of operations of the sales or other business premises. The form and contents of the form is specially prescribed with a Rulebook adopted by the Minister of Economy. The State Market Inspectorate does not adopt a special act on the basis of the report, and the establishment of requirements is carried out by regular supervision.

### **The Consumer Protection Law**

This Law regulates the protection of consumer rights, the conditions and manner of consumer protection, the requirements for trade operations relevant for consumer rights protection, the rights and obligations of consumer associations, as well as the competencies of state administration authorities as regards consumer protection.

The Law contains a provision equalling the importer to the manufacturer for the purpose of consumer protection.

A novelty in this law, in the interest of consumer protection, is the enhancement of administrative measures imposing removal of flaws within a set term. However, if the trader fails to remove the flaws within the set term, more drastic measures are applied.

### **The Law on the Quality Control of Imported Agricultural and Food Products**

The State Market Inspectorate carries quality control of agricultural and food products in foreign trade circulation on the basis of the provisions of the Law on the Quality Control of Agricultural and Food Products in Foreign trade Circulation ("Official Gazette of RM" No. 5/1998), as well as on the basis of standards and secondary legislation, i.e. rulebooks.

This law regulates the method of quality control of certain agricultural and food products, as well as their processed products, in foreign trade circulation.

Quality control of products is considered the control of the physical, chemical and organoleptic features of the product, the quantity, declaration, packaging, labelling, the means of transport and transport.

Quality control within the meaning of this law does not relate to health, veterinary and sanitary and phyto-sanitary control of product safety.

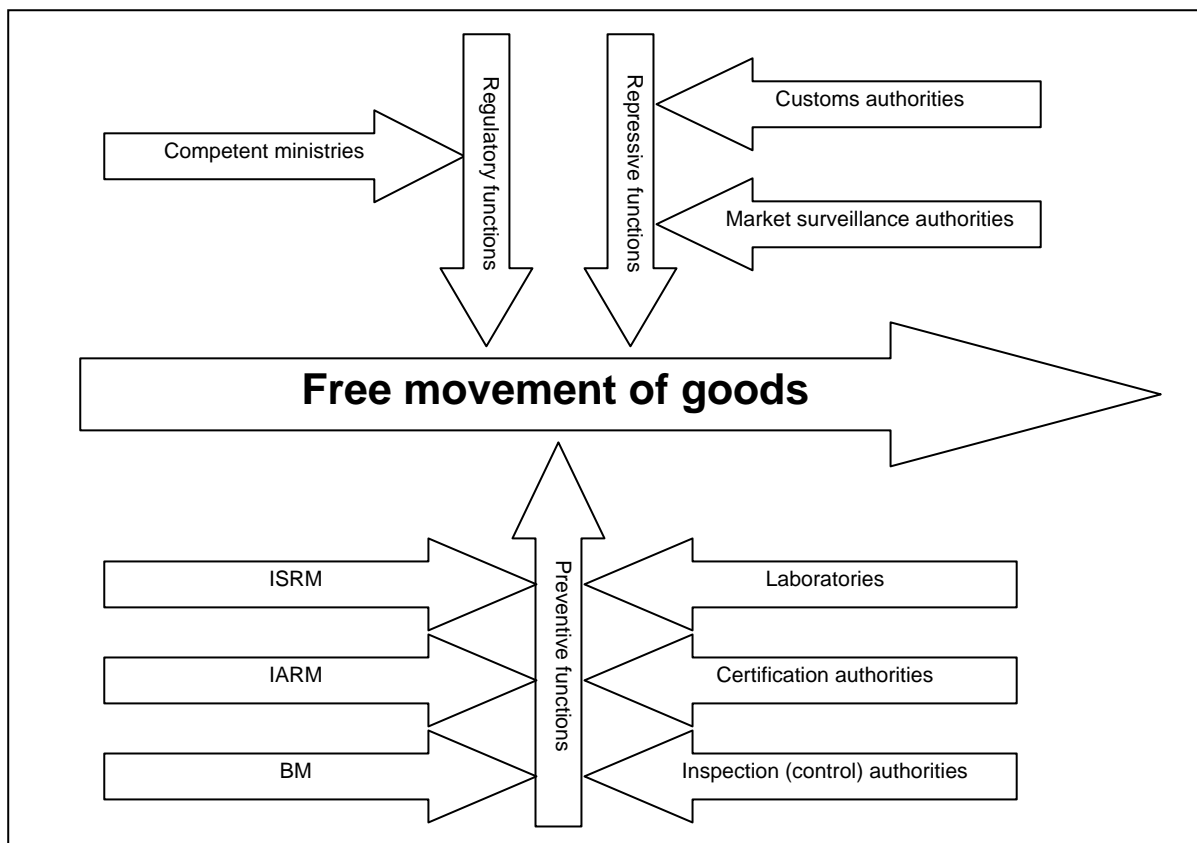
## **2. How are these functions organised, implemented and co-ordinated?**

Current structure in the Republic of Macedonia and description of the coordination and implementation of functions:

Structure:

1. The **regulatory functions** are carried out through:
  - the competent ministries:
  - the coordinator – the Ministry of Economy
2. The **repressive functions** are carried out through:
  - the customs authorities and
  - the market surveillance authorities
3. The **preventive functions** are carried out through
  - The Institute for Standardisation of the Republic of Macedonia
  - The Metrology Bureau
  - The Institute for Accreditation of the Republic of Macedonia
  - The network of laboratories, certification authorities and inspection (control) authorities

In accordance with the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02), the adoption of technical requirements (secondary legislation) is within the competence of the relevant ministries (the Ministry of Economy, the Ministry of Health, the Ministry of Agriculture, Forestry and Water Economy, the Ministry of Environment and Physical Planning, the Ministry of Transport and Communications).



### The State Market Inspectorate

The State Market Inspectorate works as a body within the Ministry of Economy. The work is carried out through the Inspection Supervision Sector and the eight departments on the territory of the Republic of Macedonia.

The Inspection Supervision Sector organises the operative activity of the departments within the sector through which state market inspectors carry out immediate inspection supervision of the application of laws and regulations and other acts in the field of trading in goods and services, quality of products and services in manufacture and trade, product prices and services in manufacturing and trade, consumer protection, quality control of agricultural and food products in foreign trade circulation, and it carries out other work stipulated by law and other regulations.

It organises cooperation at the sector and department level, cooperation among departments and institutional cooperation.

Depending on current events there is open cooperation for organising supervision together with other state authorities (the Ministry of Interior, the Public Revenue Office, the Customs Administration) and consumer associations.

The Sector also undertakes measures and activities for pre-service and in-service training of inspectors both internally and externally.

At the internal level, it organises inspector meetings in order to ensure the introduction of a principle of uniformity and unification of the procedure in the implementation and application of legal and other regulations, organises seminars, meetings and counselling for the purpose of education training and upgrading of inspectors.

At the external level, the Sector delegates and ensures participation at seminars, counselling, commissions organised by the Ministry of Economy or another institution in the Republic of Macedonia or abroad.

The inspectorate is managed by a director appointed by the Government of the Republic of Macedonia.

The operative management function is awarded to a sector manager appointed by the Minister of Economy.

The departments are managed by managers, who are also appointed by the Minister of Economy. Within the Sector there is an executive group enforcing coercive execution of executive decisions made by market inspectors concerning in-kind liabilities.

### **The Institute for Standardisation of the Republic of Macedonia (ISRM)**

The Government of the Republic of Macedonia has established the Institute for Standardisation of the Republic of Macedonia (ISRM), as a separate institution, with a view to carrying out the work and tasks in the field of standardisation, as established by the Law on Standardisation and other laws. The Standardisation Institute acts as a legal entity.

The Standardisation Institute carries out, in particular, the following tasks and activities:

- development and adoption of Macedonian standards and other standardisation documents comprising Macedonian national standardisation;
- keeping a registry of Macedonian standards;
- representing the interests of Macedonian national standardisation in international, European and regional organisations, as well as standardisation organisations in other countries;
- gathering international and European standards and standardisation documents, establishing and maintaining a database for the same, as well as standards and standardisation documents of other national standardisations;
- providing information from the database for interested parties;
- issuing a publication containing information about the commencement and course of the procedure for developing and adopting standards and standardisation documents of Macedonian national standardisation, as well as information about international and European standards and standardisation documents;
- issue and sale of standards and other standardisation documents of Macedonian national standardisation, as well as sale of international, European and other standards and standardisation documents;
- promoting the application of Macedonian standards;
- participation in the work of international and regional standardisation authorities;
- sale of standards and standardisation documents on the basis of agreements and membership of international and regional organisations, and other foreign standardisation authorities;
- carrying out the commitments in the field of standardisation arising from the international agreements the Republic of Macedonia has ratified; and
- carrying out other work and tasks concerning enforcement of the Law on Standardisation and other laws.

The work carried out by the Institute for Standardisation is not profit oriented.

Within the Standardisation Institute there is an Information Contact Authority (inquiry point).

For the purpose of developing regulations regulating technical requirements for products, in order to ensure safety of property and protection of people's life and health and of the environment, the Institute for Standardisation develops, adopts and publishes appropriate standards at the request of the Government of the Republic of Macedonia.

The Institute for Standardisation has Articles of Incorporation adopted by the Institute Assembly, regulating the name, head office location and its setup, its authorities and their competencies and responsibilities, the rights and obligations of members of the Institute, as well as other issues related to carrying out the activity for which the Institute, in accordance with this and other laws and the

incorporation act, has been established. The Articles of Association are subject to consent by the Minister of Economy.

The bodies of the Institute are as follows:

- the Assembly;
- the Council;
- the Director; and
- the Material and Financial Operations Control Board.

The Assembly consists of the members of the Institute. The Assembly is chaired by a chairman. The chairman is elected by the Assembly.

The body managing the work of the Institute is the Institute Council. The chairman and the members of the Institute Council are appointed and dismissed by the Institute Assembly from the line of eminent and competent experts in the field of standardisation for a four-year term.

The Institute is managed by a director. The director of the Institute organises and manages the work of the Institute, represents and acts on behalf of the institute with third parties and is responsible for the legality of the Institute's work. The director of the Institute is appointed and dismissed by the Council.

The decision for appointing and dismissing the director is subject to consent by the Government of the Republic of Macedonia. The director of the Institute is appointed for a four-year term and may be re-elected following the expiry of his/her term.

The Council establishes technical committees for the purpose of carrying out expert work.

Twenty technical committees have been established so far, involving more than 200 national experts, and applying 11,610 Macedonian standards. These standards are classified in 18 branches and 177 primary groups.

### **The Bureau of Metrology (BM)**

The Bureau of Metrology (BM) is established as an authority within the Ministry of Economy for the purpose of carrying out expert and other work in the field of Metrology laid down in the Metrology Law ("Official Gazette of RM" No. 55/2002) and other laws. The Bureau acts as a legal entity. The Bureau is managed by a director.

The Bureau of Metrology carries out the work and tasks in the field of the metrology system of the Republic of Macedonia related to:

- supervision of the use and writing of statutory units of measurement;
- ensuring monitoring, exercise, keeping and maintenance of national standards and certified reference materials;
- ensuring monitoring of reference standards;
- calibration of standards and measures;
- taking part in the procedure for accrediting calibration and testing laboratories on the basis of the Law on Accreditation;
- supervision of the work of legal entities authorised for carrying out certain activities in the field of metrology on the basis of this law;
- conformity assessment of the type of measures;
- verification of measures;
- the registration procedure for recognising the validity of labels and certificates for conformity of the type of measures, labels and brands, i.e. of the foreign certificates for measures verification;
- metrological supervision of the quantities and labelling of packaged products;
- expert supervision of the application of the provisions of this law and the provisions adopted on the basis of this and other laws;



- permanent training and education of employees in the Bureau and in the authorised legal entities;
- defining the work and tasks of the metrological council and taking part in its work;
- consulting services for the needs of legal and natural persons involved in circulation or use of measures;
- cooperation with other inspection authorities; and
- other work and tasks related to the enforcement of the Metrology Law and the regulations adopted on the basis of this law.

The Bureau is a member of and represents the Republic of Macedonia in international and regional organisations in the field of metrology; it cooperates with them and takes part in their work.

The Minister of economy establishes a Metrology Council operating as an expert and advisory body for the Bureau in the field of metrology.

The Bureau issues a bulletin.

### **The Institute for Accreditation of the Republic of Macedonia (IARM)**

The Government of the Republic of Macedonia has established the Institute for Accreditation of the Republic of Macedonia (IARM), as a public institution, with a view to carrying out the work and tasks in the field of accreditation, as established by the Law on Accreditation ("Official Gazette of RM" 54/02). The Institute acts as a legal entity.

The Institute for Accreditation of the Republic of Macedonia (IARM) primarily handles accreditation to:

- testing and calibration laboratories;
- product certification authorities;
- quality systems certification authorities;
- authorities certifying environmental and nature protection systems;
- person certification authorities;
- inspection authorities;

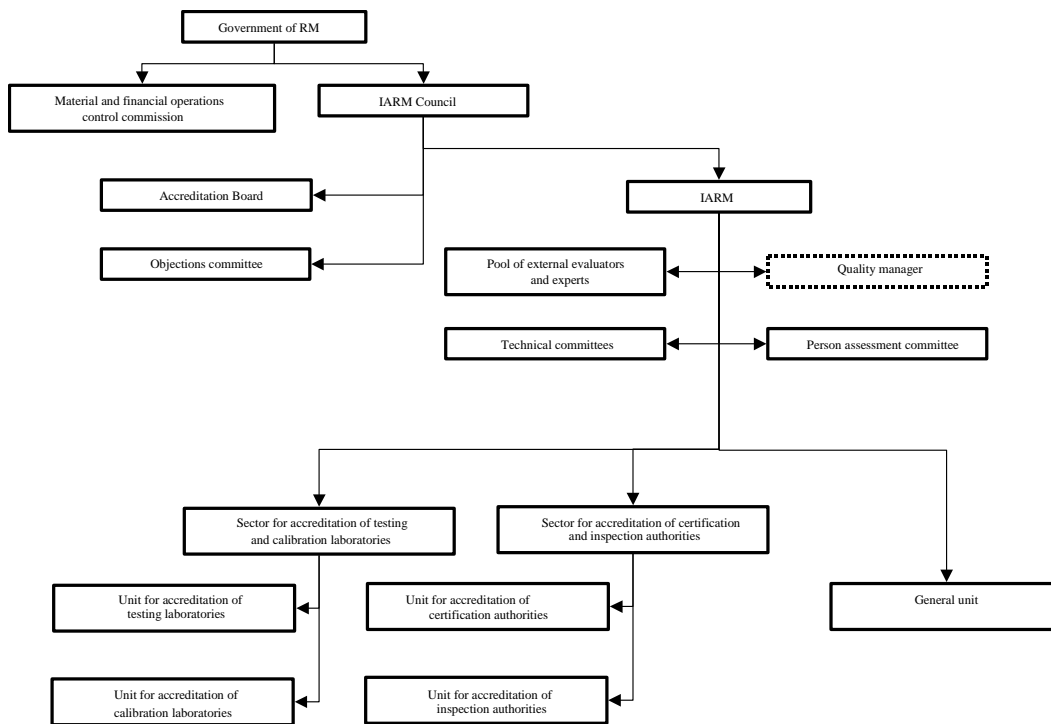
Furthermore, the Institute for Accreditation:

- is a member of and takes part in the work of European and international accreditation organisations and represents the interests of the Republic of Macedonia therein;
- provides opinions to state authorities on issues related to accreditation and provides opinions on approvals of capability to carry out the conformity assessment procedure;
- assesses and approves the competency of conformity assessment authorities, including assessment of requirements satisfaction for authorities carrying out conformity assessment according to the relevant regulations.

The Institute works in accordance with the laws and other regulations providing for the operation of public institutions, unless otherwise provided with this law.

The work carried out by the Institute is not profit oriented.

The Institute is a member of and represents the Republic of Macedonia in European and international organisations in the field of accreditation; it cooperates with them and takes part in their work.



### Laboratories, certification authorities and inspection (control) authorities

In the Republic of Macedonia there is an inherited network of laboratories, certification and inspection (control) authorities, whose status has been identified according to the old legal framework and the old principle of approval, authorisation and accreditation.

In future they will be accredited in accordance with the Law on Accreditation and the relevant international and European standards in order to assess and confirm their technical competence. Part of them are already in an accreditation procedure (more than 15 accreditation applications). In the regulated field, on the basis of accreditation, the competent minister may issue authorisation in accordance with the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02).

Within the World Bank mission from 15 September to 1 October 2004, among other things, the improvement of the quality of the system of standardisation, accreditation, metrology, certification and market surveillance has been taken into consideration for the purpose of developing a project for strengthening institutional capacity in the Republic of Macedonia for promoting economic growth and further preparation of the country for EU membership. This project component shall be carried out in cooperation with EC/EAR.

### 3. What is the basis for product conformity regulation and to what extent has your legislation moved towards the principles applied in European harmonised legislation, i.e. minimum requirements, absence of mandatory standards, self certification and the presumption of conformity?

The basis for the regulations on product conformity is, as follows:

- the Law on Standardisation ("Official Gazette of RM" No. 54/2002)
- the Metrology Law ("Official Gazette of RM" No. 55/2002)
- the Law on Accreditation ("Official Gazette of RM" No. 54/2002)
- the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/2002)
- the Consumer Protection Law ("Official Gazette of RM" No. 38/2004)
- the Trade Law ("Official Gazette of RM" No. 16/2004)

The Laws have been prepared with the technical assistance of the EU and they incorporate the principles of European law and good practice in this field.

These Laws are the basis for further implementation of technical legislation and that implementation is underway.

It is projected to adopt a Law on General Product Safety, which is covered by the GTZ project - Transposition of New Approach Directives in the National Legislation and the TWINNING project with the Republic of Slovenia - Approximation of Legislation to the Internal Market Acquis-free movement of goods, as well as to transpose 10 EU directives from the New Approach, for which a special Action Plan has been developed and it is a constituent part of the National Programme for Approximation of Legislation.

## ***B. Regulation/Administrative capacity***

**Do the relevant ministries and technical organisations have sufficient numbers of adequately trained staff to master the technicalities of law-making and to ensure adequate co-ordination? Please specify.**

In accordance with the conclusions of 22.03.2004 of the Government of the Republic of Macedonia, in the Programme for Approximation of the National Legislation to the Legislation of the European Union, the competencies of the relevant ministries have been established in terms of harmonising legislation on the planned legal regulations, i.e. implementation of EU directives from the New Approach into Macedonian Legislation.

The readiness and capability of the relevant ministries to carry out this implementation and coordination process will be assessed at the first stage of this process, aided by the SMAQV's project-Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation and the TWINNING project – Approximation of National Legislation to the Internal Market Acquis-free movement of goods, with the Republic of Slovenia, which will be a basis for the development of a detailed implementation plan.

The competent ministries which have established working groups for the implementation of EU directives of the New and Sector Approach do not currently have a sufficient number of trained staff for those tasks.

The Institute for Standardisation of the Republic of Macedonia, the Institute for Accreditation of the Republic of Macedonia and the Bureau of Metrology have adequately trained staff, but insufficient number to support the ministries which will harmonise the technical legislation of RM with the technical legislation of EU.

EU technical assistance defining the plan for restructuring the staff policy and new employment is used to enhance the capacity of the relevant ministries and technical organisations.

## ***C. Standardisation***

**1. Is the Standardisation Institute able to implement European and international standards? Has the Standardisation Institute made a needs assessment for investment and technical expertise required to participate in the European standards system?**

In accordance with the Law on Standardisation ("Official Gazette of RM" No.54/2002) and the Articles of Incorporation (December 2003), the Institute for Standardisation of the Republic of Macedonia (hereinafter: ISRM) is the national standardisation authority competent for establishing the technical

infrastructure for standardisation consisting of technical working bodies (technical committees and working groups) in whose work all stakeholders may be involved: government institutions (ministries, bodies within ministries), the economy, the industry, scientific and education institution, non-governmental citizen associations, the chamber of commerce etc.

Twenty technical committees have been established so far involving more than 200 experts in the areas the committees cover. There is an analysis of the current status of activities and of the need for future activities in the field of standardisation. On the basis of this analysis, a proposal has been developed for establishing the necessary technical infrastructure (technical committees) for adopting the European standards as Macedonian. It is projected to establish forty more technical committees in the course of three stages in the subsequent three-year period, adding up to a total of sixty technical committees whose scope of operations will cover the work on CEN, CENELEC and ETSI.

The process of harmonising the technical legislation in the Republic of Macedonia with EU legislation is within the competence of the relevant ministries. This process also determines the dynamics of transposition of European standards. Taking into consideration the current situation and the expected future development, the taking European standards as Macedonian will largely be carried out by the endorsement method.

There is an appraisal of the number of harmonised EU standards from the ten New Approach directives designated as a priority for implementation in the legislation of the Republic of Macedonia. In accordance with the requirements for accession membership of European standardisation organisations, ISRM plans to improve the technical knowledge necessary for participation in the European standardisation system. The following has been provided within the national CARDS programme – the SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation (1 July 2003 – 31 October 2004):

- IT (hardware) and telecommunications equipment,
- trainings and seminars.

The new IT and telecommunications equipment presents a basis for establishing a new information system that will support national standardisation in its participation in European standardisation.

An additional training programme is planned for all parties interested in standardisation, which will improve the technical knowledge required for participation in the European standardisation system.

ISRM has made an appraisal of the investment needs for the following:

- additional staffing
- training, fifteen trainings have been projected within the CARDS–SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation project, participation of ISRM representatives in the CARDS Twinning project between the Republic of Macedonia and the Republic of Slovenia - Approximation of legislation to the Internal Market Acquis – free movement of goods;
- creating a software for managing the ISRM information system;
- investments for carrying out the process of taking European standards as Macedonian.

ISRM has made an appraisal of investments for 2005 for transposing harmonised European standards from the New Approach directives. This appraisal is contained in the Budget for 2005.

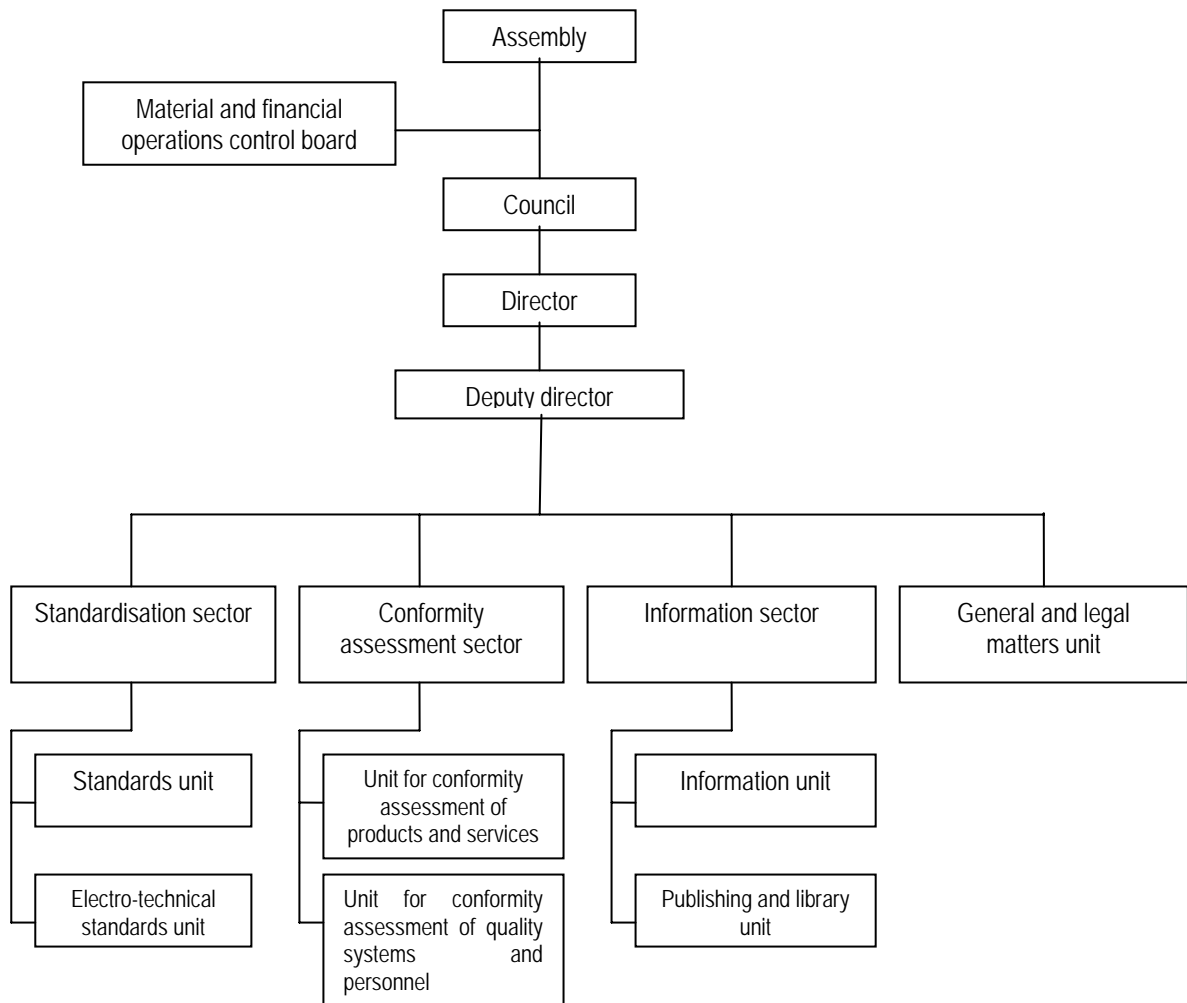
## **2. Are staff numbers and financing adequate?**

The Institute for Standardisation of the Republic of Macedonia currently has eight (8), employees which is insufficient for carrying out all the work and tasks assigned to ISRM.

In accordance with the newly adopted organisation and systematisation of the Institute for Standardisation, it is provided for the total number of employees to increase to 27.

In accordance with Article 19 of the Law on Standardisation, the work and tasks are financed from the Budget of the Republic of Macedonia and from revenue generated from the Institute for Standardisation.

STANDARDISATION INSTITUTE OF THE REPUBLIC OF MACEDONIA  
Organisation scheme



**3. What percentage of your standards is in conformity with European standards (give separate percentages for CEN, CENELEC and ETSI standards)?**

The basis for preparation of the Programme for adopting European Standards as Macedonian in 2005 is the process of implementation of the ten New Approach directives designated as a priority for the Republic of Macedonia. It is planned to adopt European harmonised standards as Macedonian standards largely by the endorsement method.

Five European standards in the field of thermal insulation have been adopted hitherto.

The following European standards are in the process of being adopted as Macedonian standards by translation into Macedonian:

- 20 in the field of civil engineering;
- 2 in the field of non-destructive examinations – terminology; and
- 2 in the field of oil derivatives.

For the purpose of improvement of the quality infrastructure, the following activities have been targeted for the upcoming period in the field of standardisation:

- introduction of a system for fast adoption of European standards; and
- modernisation of databases for electronic filing and distribution of standards.

**4. Please indicate (work towards) membership of European and international standards organisations (CEN, CENELEC, ETSI, others). Is there a timetable for achievement of full**

**membership of CEN and CENELEC? What is the relationship with the international (IEC and ISO) standards bodies?**

Since 01.01.1995 the Institute for Standardisation of the Republic of Macedonia has been a full-fledged member of the International Organisation for Standardisation – ISO. The Institute for Standardisation is a full-fledged member in one ISO technical committee and an observer in two technical committees. Due to the lack of funding the work at the meetings of technical committees is insignificant.

Since 2001 ISRM (previously the Bureau of Standardisation and Metrology) has taken part in the IEC Accession Members Programme. For the purpose of satisfying the accession membership requirements for CENELEC, ISRM applied for associative membership of IEC on 13.09.2004 in Geneva.

Starting from 14.01.2005, the Institute for Standardisation of the Republic of Macedonia has become an associative member of IEC.

ISRM, as the national standardisation authority of the Republic of Macedonia, has been an accession member of CEN since 01.07.2003.

There are negotiations for applying and initiating the procedure for accession membership of CENELEC. The necessary preparations have been carried out and the required documentation for accession membership of CENELEC has been prepared. The application for accession membership of CENELEC was submitted on 17.11.2004.

It is planned to apply for membership of ETSI.

The activities of Macedonian standardisation are focused on accelerated preparations for meeting the nine requirements (legal, organisational and technical) for obtaining the status of a full-fledged member of CEN and CENELEC.

The timeline for achieving full-fledged membership of CEN and CENELEC for the Republic of Macedonia is targeted for at least five to six years.

***D. Accreditation***

**1. Does your country have an accreditation system and an accreditation body? Is the body independent? Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting certification bodies in line with the European system?**

**Does your country have an accreditation system and an accreditation body?**

Yes, the Institute for Accreditation of the Republic of Macedonia (IARM) is the only national accreditation authority.

The framework for the operation of IARM is based on:

- the Law on Accreditation (“Official Gazette of RM” No. 54/2002)
- the Decision of the Government of the Republic of Macedonia to establish IARM;
- the IARM Articles of Incorporation;
- the acts of the IARM Council;
- the acts of the IARM director;
- international and European standards;
- the EA, ILAC and IAF documents.

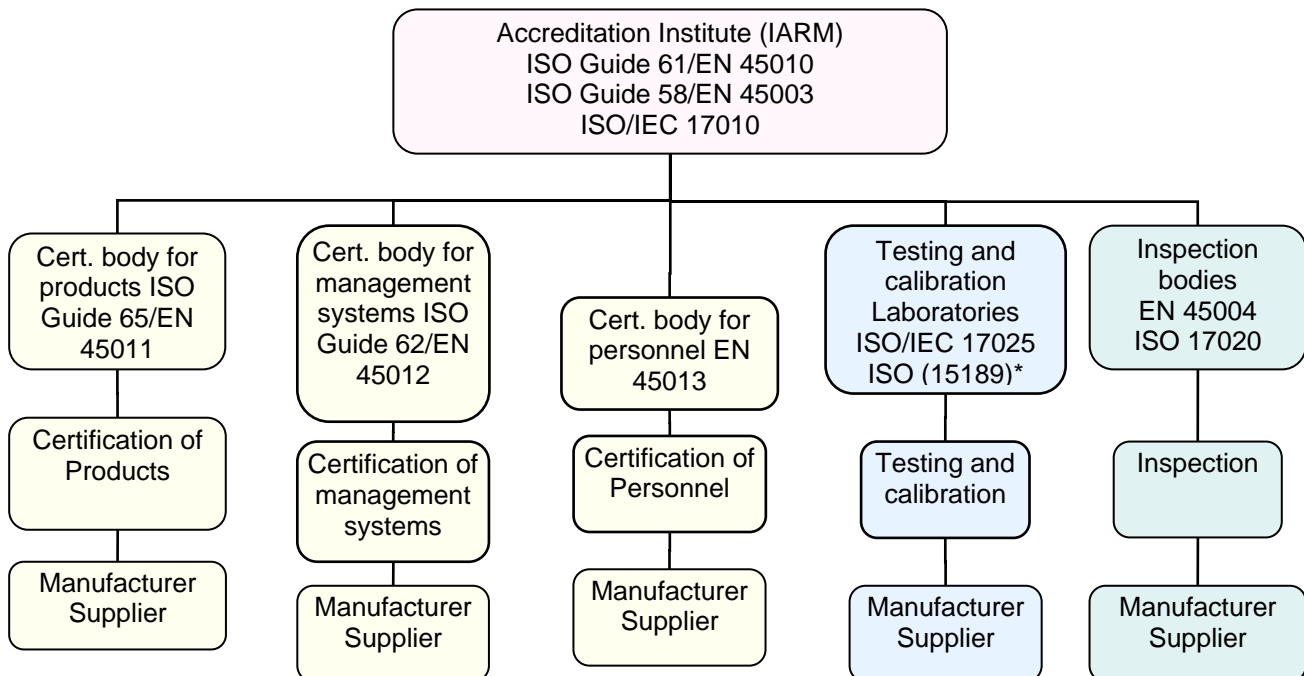
### Is the body independent?

Yes, IARM is an independent in its activities and decisions. The work of IARM is based on the following principles:

- transparency and accessibility;
- representation of public interests;
- voluntary character of accreditation;
- independence;
- impartiality;
- harmonisation and equivalence of procedures;
- non-discrimination;
- confidence building with clients;
- data protection;
- non-profit operation.

These principles have been incorporated in the documents constituting the operation framework of IARM.

### Standards of work of IARM



\* for medical laboratories

### Does it have the full range of technical and administrative competencies necessary for the purpose of accrediting certification bodies in line with the European system?

Yes, IARM has the minimum technical and administrative competencies required for accreditation.

It has the following:

- adequately organised offices, sufficient for accommodating all projected workers in accordance with the systematisation and organisation of IARM;
- within the SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation, by the end of 2004, it will be equipped with the latest IT equipment.

The offices and bodies through which IARM carries out its functions are:

- the Council;
- the director;
- the Material and Financial Operations Control Board:

- the Accreditation Board;
- the assessment commissions;
- the technical committees;
- the evaluators and experts committee;
- the objections committee.

All the IARM infrastructure i.e offices and bodies have been established.

## **2. Does it have agreements with European or other international organisations?**

IARM has not signed agreements with European or other international accreditation organisations.

## **3. Is it a member or working towards membership of any such organisations?**

The Institute for Accreditation of the Republic of Macedonia (IARM) applied for membership of EA (the European accreditation organisation) in October 2004.

It is also planned that in 2005 IARM will apply for membership of two international accreditation organisations - IAF (the International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation).

## ***E. Certification / testing / inspection***

### **1. What relevant bodies (and in which product sectors) does your country have in these areas? Have you made an assessment of these as regards laboratory practice, equipment and staff training needs?**

#### ***What relevant bodies (and in which product sectors) does your country have in these areas?***

In the Republic of Macedonia there is an inherited network of laboratories, certification and inspection (control) authorities, whose status has been identified according to the old legal framework and old principle of approval, authorisation and accreditation.

In future they will be accredited in accordance with the Law on Accreditation and the relevant international and European standards in order to assess and confirm their technical competence. Part of them is already in an accreditation procedure (more than 15 accreditation applications).

In the regulated field, on the basis of accreditation, the competent minister may issue authorisation in accordance with the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02)

We may sum up that there is an apparent need in the Republic of Macedonia for:

- Ensuring conditions for product certification by Macedonian certification authorities whose certificates are recognised by the European and international market, as well as introduction of the principles of a global and modular approach in the conformity procedure.
- Introducing national certification authorities who will work in accordance with the criteria laid down in the MKS EN 450 11 and 450 012 standards and which will be competent for product certification.



***Have you made an assessment of these as regards laboratory practice, equipment and staff training needs?***

An assessment of the situation with laboratories, certification and inspection (control) authorities has been developed in the study within the CARDS–SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation (premises, equipment, staff, problems).

The study determines the activities targeted as necessary to be carried out in the Republic of Macedonia:

1. Development of a national conformity assessment system to enable the implementation of product safety requirements, with priority to the areas of interest for the Republic of Macedonia;
2. The transposition of EU directives from the New Approach and establishing a functional infrastructure for conformity assessment, based on the principles of the EU New Global Approach, must ensure free movement of industrial products;

Transposed directives and a developed national conformity assessment system are a basis for signing the PECA protocols guaranteeing the free movement of industrial products;

Furthermore, in future, the state authorities for market surveillance will not be able to operate soundly without a developed conformity assessment system.

The study proposes to:

1. Develop a document: Strategy for developing and upgrading the national conformity assessment system based on the principles of the EU New and Global approach;
2. Establish the priority areas covered, in particular, by the New Approach EU directives;
3. Define which requirements must be satisfied for the competent operation of the national conformity assessment system in the priority areas (independence, impartiality etc.);
4. Ensure EU technical assistance for personnel training;
5. Identify possible funding sources for procuring the appropriate equipment;
6. Ensure funds to prepare the bodies for conformity assessment of accreditation;
7. Determine the organisational concept of the national conformity assessment system (distributed, integrated or combined).

Working towards accomplishing the aforementioned activities, within the CARDS–SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation, in accordance with Articles 5, 68 and 73 of the SAA, the key objective for providing technical assistance for the implementation and unhindered operation of the targeted infrastructure has been achieved, and a sound basis created for implementing the projected activities.

## ***F. Metrology***

### **1. What is the present metrology structure in your country?**

The current metrological infrastructure is entirely oriented towards legal metrology and it is maintained well. This infrastructure is inherited from the former Law on Measurement Units and Measures in addition to the inherited technical regulations related to legal metrology, which are largely in accordance with the OIML recommendations - the International Organisation of Legal Metrology.

The greater part of these regulations are still in force and this is related to the metrological regulations on the conformity assessment of certain categories of measures that are much more numerous than the scope of the MID directive and the realistic capacity of the Bureau of Metrology for their implementation.

The Bureau of Metrology verifies mass measuring instruments: measures for mass scales and weights of all types, water gauges, electric meters, taximeters, liquid fuel gauges, thermal energy meters, dosing and packaging control machines, control of precious metal items and others.

Traceability of the measuring instruments through the Bureau of Metrology is difficult to ensure due to, in particular, inadequate equipment and lack of technical personnel, while infrastructure users individually provide monitoring and calibration by foreign institutions. The system of metrology laboratories (authorised and approved) that the Bureau of Metrology coordinates administratively still exists.

The authorised laboratories are legal entities authorised by the Minister of Economy and they meet the requirements for carrying out certain metrological activities – inspection of conformity of the features of the measuring instrument prescribed with a special technical regulation.

Approved laboratories are not a special category of the Metrology Law. They were defined by the previous law on units of measurement and measuring instruments. They are legal entities ensuring conditions (equipment, premises and trained personnel) for conformity assessment – verification of the measuring instrument by an officer from the Bureau of Metrology concerning the features of the measuring instrument prescribed by a special technical regulation.

These entities have been informed of the next steps they must take for their integration in the new legal framework for the infrastructure of quality through several purpose-oriented workshops and seminars and they have started to grasp the need of introducing quality systems, especially ISO 17025 for calibration laboratories and evaluation of their competence through the accreditation process. In the transition period, a special Government regulation on approved laboratories has introduced a partnership relationship of agreement with the Bureau of Metrology pending their transition in the new system by asserting their competence through accreditation.

In certain areas that are not traditional for legal metrology, there is scientific metrology (seismology, genetics, and biochemistry) and they need to be integrated in the metrology system.

## **2. Is there a national programme for the development of the metrology structure?**

The constitution of the Metrology Council provided a sound basis for the future development of national policies, strategies and programmes for progress in metrology. A draft policy for metrology and a short-term (two-year) development programme on the metrology infrastructure has been prepared and submitted for further Government procedure.

This programme is based on the screening of the metrology infrastructure and the recommendations of the experts from the CARDS/SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation, as well as on the existing documents in this field, such as the National Quality Programme of the Republic of Macedonia and the Action Plan for developing the necessary organisation infrastructure and human resources for meeting the requirements contained in Article 73 of the SAA, and on the adopted policy for developing the national metrology infrastructure, provided below:

- Building a competent and independent national metrology institution;
- Relying on national resources, including available scientific and technological potential, and on the basis of the support from the international community for metrology infrastructure, a special basis will be provided for the development of the Bureau for Metrology as a carrier of the metrology infrastructure, as well as of its calibration capacities;
- Establishing national standards and laboratories;
- In particular, guided by the needs and requests of the state, economy and consumer, citizen and environment protection, the relevant national standards and laboratories will be provided;
- Providing a basis for certification and inspection activities;
- The basis will consist of adequate metrology equipment and know-how of the Bureau for Metrology;
- International recognition of the national metrological infrastructure;
- Ensure a recognizable Macedonian metrological infrastructure both nationally and internationally, as well as membership of European and international metrology organisations

and institutions, through continuous activities, international agreements and international cooperation;

- Identifying the necessary areas for sustainable development of our metrological infrastructure;
- The areas for sustainable development will be identified on the basis of the particularities of the Macedonian economy and industry in the world globalisation trends;
- Information and promotion activities for metrology;
- Activities will be organised for building and promoting the national metrological infrastructure by organising workshops on metrology subjects; and
- Active participation in the work of international organisations.

### 3. How is traceability to international measurement standards ensured?

The Republic of Macedonia, represented by the Bureau of Metrology, has been a full-fledged member country of OIML – the International Organisation of Legal Metrology – since 1994. A procedure has been initiated before BIPM (the International Bureau of Weights and Measures) in Paris for accomplishing accession membership of CGPM (the General Conference on Weights and Measures) and, thus, of the Meter Convention, with a possibility to sign the MRA (Mutual Recognition Arrangement for calibration and measurement certificates, as one of the requirements for membership of the regional European metrology organisation - EUROMET – through which measurement monitoring may be most adequately ensured.

The current situation is explained in detail in the answer to [01 II B. 1](#). a) first paragraph, and b) contains the explanation for further development.

Recently, the Bureau of Metrology, through the PHARE/PRAQ III programme, took part with its modest technical abilities in the intra comparisons of the metrology institutions of Southeast Europe for mass, length and electrical measures, as well as calibration of their national standards in European calibration laboratories. Technical assistance is necessary for introducing a quality system in the Bureau of Metrology, as one of the requirements for meeting EN ISO 17025 in the laboratory centre of the Bureau, as well as technical assistance for preparation for accession to EUROMET.

## G. Market surveillance

**How does your country ensure that products on the market throughout the country meet standard requirements? (Alternatively, do you have a reliable and standardised system of pre-marketing authorisation?) How is co-ordination ensured between sectors? How is market surveillance co-ordinated between market surveillance authorities and customs as regards product conformity and safety checks at external borders? What information exchange network exists between the various authorities?**

In the Republic of Macedonia there is an inherited network of laboratories, certification and inspection (control) authorities, whose status have been identified according to the old legal framework and the old mechanism of approval, authorisation and accreditation.

Product liability lies with the manufacturers prior to releasing them into circulation or utilizing them. Testing, certification, i.e. inspection (control) of the product is performed by adequate conformity authorities. This arises from the transitory provisions of the Law on Standardisation, the Law on Accreditation, the Metrology Law and the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02), according to which the regulations laying down technical requirements for products, the procedure for assessing their conformity with technical requirements, product marking, as well as the necessary paperwork accompanying products, are carried out in accordance with the regulations adopted on the basis of the Law on Standardisation of 1995 ("Official Gazette of RM" No. 23/95).

Coordination among market surveillance authorities (inspection services) is carried out pursuant to the Law on General Administrative Procedure, the Law on the Organisation and Work of State

Administration Bodies ("Official Gazette of RM" No. 58/2000 and 44/2002), as well as the special laws of inspection bodies regulating the competencies of each state administration body.

Prior to commencing the customs clearance procedure, the State Market Inspectorate carries out inspection supervision of goods (non-food products) regarding the declaration and instruction for use, which must be in Macedonian and in Cyrillic letters on the original packaging, which does not exclude the possibility for simultaneous use of other languages and signs easily understandable for buyers, and it compiles a document (minutes) on the basis of which the competent customs authority carries out customs clearance for the goods.

Information exchange among different competent authorities is carried out continuously and with permanent mutual contacts.

## ***H. International Agreements***

**1. What mutual recognition or co-operation agreements in the field of standards, testing, certification and conformity assessment has your country signed? Do such agreements use international standards as a basis? Please provide translated copies (in English) of the relevant agreements.**

The Republic of Macedonia has agreements for mutual cooperation in the field of standardisation, metrology, accreditation and conformity assessment, as follows (copies of the agreements are attached):

1. Agreement between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the State Bureau of Standardisation and Metrology of the Republic of Croatia; - see [01 Annex 01](#)
2. Agreement between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the Federal Bureau of Standardisation and Metrology of the Republic of Yugoslavia;- see [01 Annex 02](#)
3. Agreement between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the State Committee of the Russian Federation on Standardisation, Metrology and Certification for Recognising the Results from the Examinations of Imported Goods; and – see [01 Annex 03](#)
4. Agreement between the Government of the Republic of Macedonia and the Cabinet of Ministers of Ukraine for cooperation in the field of mutual recognition of reports for establishing conformity assessment;-see [01 Annex 04](#)

Cooperation protocols and memoranda are, as follows:

1. Memorandum of understanding between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the Netherlands Institute for Metrology
2. Memorandum of understanding between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the UK National Weights and Measures Laboratory
3. Memorandum of understanding between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the National Metrology Institute of the Republic of Turkey
4. Memorandum of understanding between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the Czech Office for Standardisation, Metrology and Testing. – see [01 Annex 05](#)
5. Cooperation protocol between the Bureau of Standardisation and Metrology of the Republic of Macedonia and the Federal Bureau of Measures and Precious Metals of the Federal Republic of Yugoslavia

## II. SECTOR SPECIFIC LEGISLATION

### A. Competent authority/ies

#### 1. Please provide information regarding the:

(The answer should be in two parts, to cover industry in general and each of the individual sectors listed in Chapter 15 of the questionnaire, section II)

- a) present status, including a description of the present type approval system for each sub-sector listed in Chapter 15.I, Section II of this questionnaire;
- b) forecast (date of adoption and implementation of the EU directives).

#### a)

The Government of the Republic of Macedonia has adopted National Programme for Approximation of Legislation (NPAL), incorporating the Action Plan for approximation of technical standardisation - technical regulations. The National Programme contains technical regulations from other relevant ministries competent for harmonising legislation, which are related to industry sectors within the scope of the industrial policy. In the following period, within the programming, it is expected that the Action Plan will be appended with other technical regulations that need to be transposed.

The same commitments for adjusting to EU standards have been undertaken with the Action Plan for European Partnership.

In that respect, the following laws were adopted and enforced in 2002:

- The Law on Standardisation ("Official Gazette of RM" No. 54/2002)
- The Law on Accreditation ("Official Gazette of RM" No. 54/2002)
- The Metrology Law ("Official Gazette of RM" No. 55/2002)
- The Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02)

The above are entirely in line with European legislation.

The 1995 Law on Standardisation ("Official Gazette of RM" No. 23/95) adopted the regulations, secondary legislation and standards from the former SFRY 11,610 JUS standards as Macedonian.

The majority of regulations and secondary legislation acts (rulebooks on quality, orders for mandatory attestation, rulebooks on technical standards, and etc.) have not been revoked and are still in application, i.e. are enforced by the competent ministries and bodies within the ministries. The majority of standards were mandatory.

With the new Law on Standardisation ("Official Gazette of RM" No. 54/02) all Macedonian standards are voluntary. In accordance with the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02), technical requirements are within the competence of the relevant ministries.

Macedonian standards are grouped in 18 branches, as follows:

- Branch A: Elementary and general standards (6 primary groups) - a total of 101 standards
- Branch B: Mining and processing minerals, oils and oil (10 primary groups) - a total of 1,138 standards
- Branch C: Metallurgy and metal processing technology (13 primary groups) – a total of 1,079 standards
- Branch D: Forestry, timber and wood industry and processing wood materials (11 primary groups) – a total of 559 standards

- Branch E: Agriculture, food and tobacco industry (9 primary groups) – a total of 397 standards
- Branch F: Textile and clothing industry (8 primary groups) – a total of 321 standards
- Branch G: Leather, rubber and plastic materials industry (8 primary groups) – a total of 446 standards
- Branch H: Chemical industry (14 primary groups) – a total of 1,724 standards
- Branch I: Information technology and data processing (7 primary groups) – a total of 62 standards
- Branch J: Energy (1 primary group) – a total of 2 standards
- Branch K: Tools and accessories industry (16 primary groups) – a total of 842 standards
- Branch L: Measuring and other accurate mechanical devices industry (10 primary groups) – a total of 100 standards
- Branch M: Machine construction and metal industry (15 primary groups) – a total of 1,726 standards
- Branch N: Electro-technology (15 primary groups) – a total of 1,784 standards
- Branch P: Devices, plants and railroad vehicles (10 primary groups) – a total of 367 standards
- Branch R: Ship building, devices and plants for river and sea traffic (1 primary group) – a total of 1 standard
- Branch U: Civil engineering (12 primary groups) - a total of 533 standards
- Branch Z: Standards not belonging to any special group (10 primary groups) – a total of 428 standards.

Existing Macedonian standards are not harmonised with European ones, except for branch U: civil engineering, where five European standards in the field of thermal insulation have been adopted as Macedonian standards.

See for more details in [01 I C 3](#).

#### **A. Raw materials, non-ferrous metals, ferro alloy, cement, glass, ceramics, paper and wood, publishing industry**

Existing relevant technical regulations on raw materials, non-ferrous metals, ferro alloy, cement, glass, ceramics, paper and wood, publishing industry (18 rulebooks and 6 decrees) applied in this field are still not harmonised with European regulations.

See more details in Chapter 15: [15 I II A](#).

#### **B. Chemical products and rubber**

The field of chemical products and rubber is regulated with the existing regulations and laws, where national legislation distinguishes chemicals according to the needs of each law respectively.

- Rulebook on Marketing Products of General Use (“Official Gazette of RM” No. 26/83)
- Law on Production of Toxins (“Official Gazette of RM” No. 18/76)
- Law on Traffic of Toxins (“Official Gazette of RM” No. 13/91)
- Law on Transport of Dangerous Materials (“Official Gazette of RM” No. 12/93)
- Law on Pharmaceutical Drugs, Supplementary Treatment Substances and Medical Devices (“Official Gazette of RM” No. 21/98)
- Law on Precursors (“Official Gazette of RM” No. 37/2004)
- Law on Labelling Toxic Substances Entering the Domestic Market (Official Gazette of the SFRY No. 32/86)
- Rulebook on the Manner of Destruction of Unused Toxins and Materials Used for Packaging Toxins and the Procedure of Withdrawing Toxins from Sale (Official Gazette of the SFRY No. 7/83).
- Law on Plant Protection (“Official Gazette of RM” No. 25/98) and Amendments to the Law (“Official Gazette of RM” No. 6/2000)

- Rulebook on Conditions Requirements for Legal Entities Concerning the Tools, Equipment and Premises Used in Production, Wholesaling and Retailing of Plant Protection Chemicals and on Contents and Bookkeeping of the Register (“Official Gazette of RM” No. 54/2001).

The pneumatics (tyres) intended for use of road vehicles fulfill the regulations determined by Homologation Order UN ECE R54 - Order on Mandatory Homologation of tyres of Commercial Vehicles and their Trailers, except for Passenger Vehicles (Official Gazette of the SFRY No. 11/85) which was renewed and adopted by the Homologation Order for compulsory A-Test of vehicles on wheels, equipment and parts which can be built in and/or used in vehicles on wheels (“Official Gazette of RM” No. 89/2000, 95/2001, 21/2002, 45/2002, 35/2004)

The pneumatics (tyres) for tractors and their trailers are regulated by Commission Regulation (EC) No 106/2000 of 18 January 2000, and repaired tyres for motor vehicles and their trailers from vehicle categories M, H, O must meet the requirements of EC Guidelines No. 108 and 109 in the previously stated Guidelines.

See more details in Chapter 15: [15 I II A](#).

### **C. Machine engineering, electrics and consumption electronics**

The field of machine engineering, electrics and consumption electronics is regulated with existing regulations and, at the same time, with the new law that are harmonised with those of the EU, as follows: the Law on Standardisation, the Law on Accreditation, the Metrology Law, and the Law on Prescribing Technical Requirements for Products and Conformity Assessment (“Official Gazette of RM” No. 55/02). There are 54 technical rulebooks and eight decrees in this field which are still not harmonised with European regulations.

See more details in Chapter 15: [15 I II A](#)

### **D. Information technology industry**

Secondary Legislation relating to telecommunications terminal equipment in which the Directive 98/13/EEC will be harmonised and it will be transposed by the Ministry of Transport and Communications in 2005/2006;

Directive 98/48/EEC amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations for information services (will be transposed with the Law on Electronic communications which is in Parliamentary procedure);

### **E. Pressure vessels, medical devices, measuring instruments, medical devices, including active medical devices and test-tube instruments**

The State Technical Inspectorate, as a body within the Ministry of Economy, is responsible for enforcing the laws and regulations regulating this field, as follows:

- construction and reconstruction of steam boilers;
- construction, reconstruction, embodying, production and use of water heating boilers, stable pressure vessels, as well as all equipment considered as devices under pressure;
- technical features and structure of material used for processing, production of steam boilers and pressure vessels;
- fulfilment of working conditions for employees who operate with steam boilers;
- fulfilment of conditions of legal and physical entities, dealing with designing, construction, manufacture and installation and use of steam machines and boilers;

Our national legislation regulates all procedures for medical aids (devices) with the Law on Drugs, Additional Medicines and Medical Devices (“Official Gazette of RM” No. 21/98). At present, a working group is preparing a new Rulebook on Medical Devices in accordance with the European directives.

The following bylaws will be adopted in accordance with the Action Plan within 2005/2006:

- Bylaws relating to pressure vessels where the Directives 87/404/EEC, 90/488/EEC and 93/68/EEC will be harmonised.



- Bylaw relating to appliances burning gaseous fuels 90/396/EEC, 93/68/EEC
- Bylaw relating hot-water boilers will be harmonized with Council Directive 92/42/EEC
- Bylaw concerning medical devices will be harmonised with Council Directive 93/42/EEC.
- Bylaw on diagnostic medical devices where the Directive 98/79/EC of the European Parliament and of the Council will be harmonized.

## **F. Civil engineering and construction products**

In this field there are 51 regulations (1 law, 4 orders, i.e. decrees and 46 rulebooks) valid, which are still not harmonised with EU standards.

The Law on Construction with accompanying bylaws are in their final stage of preparation, and their adoption and implementation is expected in 2005;

The preparation of Law on Building Materials and Bylaws will begin in 2005, and its adoption is expected in 2006. These legal acts are completely harmonized with Council Directive 89/106/EEC relating to construction products.

## **G. Transport Equipment Industry**

In this field 22 regulations are applied, which are still not harmonised.

The Republic of Macedonia has continuity in the homologation of road vehicles since 1962 on the basis of succession of SFRY by acceptance of the Geneva Convention of 1958 accepted by the Republic of Macedonia on 17 November 1991. ("Official Gazette of RM" No. 89/2000, 95/2000, 21/2002, 45/2002, 35/2004).

On the basis of the accepted Geneva Convention, several homologation orders have been published, as follows:

- Order for compulsory attesting (homologation) of vehicles on wheels, equipment and parts which can be built in and/or used for vehicles on wheels ("Official Gazette of RM" No. 89/2000; 95/2001; 21/2002; 45/2002; 35/2004).
- Order for compulsory attesting (homologation) of the vehicles on wheels of the equipment and parts from motor vehicles ("Official Gazette of RM" No. 84/2001; 21/2002; 31/2002; 52/2002; 26/2004; 35/2004).

By adoption of the Amendments to the Law on Transport in Road Traffic Safety ("Official Gazette of RM" No. 14/98; 38/2004) and the Law on Prescribing Technical Requirements for Products and Conformity Assessment ("Official Gazette of RM" No. 55/02) a legal base is created, through the adopted ECE homologation Rulebooks for vehicle categories L, M, N, O and the corresponding ECE Directives to implement the directives relating to the homologation of the vehicles as a whole.

Automatism is also implemented in the procedure of adopting the ECE Rulebooks, and in the national legislation dynamics is introduced for certain Rulebooks through the ECE Rulebooks i.e. through EEC Directives to become completely harmonised in the implementation of the European Directives in this field.

## **H. Foodstuffs**

In the preparation of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02), the Regulation (EC) No **178/2002** of the European Parliament and of the Council is taken as a basis.

The law is normative-technically prepared to be internationally acceptable, having both horizontal and vertical regulation (Basic Law and a large number of Bylaws). The analogy of this law is found in the structure of *Codex Alimentarius* and in the structure of the European Food Legislation.



National legislation in the Republic of Macedonia in the field of sanitary safety of food is still not in full compliance with international standards, however, the adoption of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02)stuffs and Food Contact Products and Materials is based on EU regulations: Directive 2000/13/EC, Regulation (EEC) 2008/92 of the Council, Directive 2001/18/EC, Directive 93/99/EEC of the Council, Regulation (EC) 258/97 of the European Parliament and of the Council.

See more details in Chapter (01 – [III. D](#)) and Chapter 15: [15. I II A](#).

### **I. Textile and clothing, leather, footwear, furniture, toys**

- Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys.
- Council Directive 93/68/EEC of 22 July 1993 amending Directive 88/378/EEC (safety of toys).
- Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, is implemented in the Rulebook on characteristics of the toys for sale ("Official Gazette of RM" No. 90/2004), which is in accordance with the Consumer Protection Law ("Official Gazette of RM" No. 38/2004).
- Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer.

Bylaw on Law on Regulation of Technical Requirements for Products and Assessment of Conformity – Labeling of the materials used in the main components of footwear

- Directive 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names.
- Council Directive 73/44/EEC of 26 February 1973 on the approximation of the laws of the Member States relating to the quantitative analysis of ternary fibre mixtures.

Bylaw on Law on Regulation of Technical Requirements for Products and assessment of Conformity relating to the quantitative analysis of ternary fibre mixtures

- Directive 96/73/EC of the European Parliament and of the Council of 16 December 1996 on certain methods for the quantitative analysis of binary textile fibre mixtures.

Bylaw on the Law on Regulation of Technical Requirements for Products and Assessment of Conformity on certain methods

### **J. Pharmaceutical Products**

#### **1. Drugs for human use**

Valid legal regulations in the field of drugs for human use:

- the Law on Pharmaceutical Drugs, Supplementary Treatment Substances and Medical Devices ("Official Gazette of RM" No. 21/98)
- Instruction on procedures for approving and placing a final drug in circulation ("Official Gazette of RM" No. 49/04)
- Rulebook on the requirements for premises equipment and staff that must be satisfied by the legal entities carrying out wholesale of drugs, additional drugs and medical accessories ("Official Gazette of RM" No. 64/02)
- Rulebook on prescribing and issuing drugs ("Official Gazette of RM" 17/02)
- Rulebook on organising the monitoring of the reporting and on the data related to established undesirable side effects of using a medicine (Official Gazette of SFRY 57/87)
- Rulebook on clinical drug testing (Official Gazette of SFRY 2/89)
- Instruction on the methods of laboratory testing of drugs for their placement in circulation ("Official Gazette of SFRY" 34/89)
- Order for drugs subject to special control when placing in circulation ("Official Gazette of RM" No. 22/88)

- Decision for drug classification (Official Gazette of SFRY 47/85, 73/85, 54/90)

## **2. Veterinary medical products**

The field of medical products used in veterinary medicine is regulated with two laws:

1. Law on Pharmaceutical Drugs, Supplementary Treatment Substances and Medical Devices ("Official Gazette of RM" No. 21/98)
2. Law on Veterinary Healthcare ("Official Gazette of RM" No. 28/98).
  - Rulebook on reporting undesirable side effects of the use of drugs and incidents caused by medical accessories, as well as on their monitoring, collection and recording ("Official Gazette of RM" No. 39/2002)
  - Rulebook on the requirements for legal entities carrying out wholesale of drugs, additional drugs and medical accessories in veterinary medicine regarding the premises, equipment and staff ("Official Gazette of RM" No. 39/2002).

### **b)**

In 2004 the Government of the Republic of Macedonia adopted National Programme on Harmonisation of Legislation of the Republic of Macedonia with European legislation, providing timelines for adopting laws and secondary legislation.

The new proposals planned for 2005 are: the Law on Consumer Goods Safety, which is to transpose the Directive 92/59/EEC revised with 95/01/EEC and secondary legislation on CE marking wherein the Directive 93/68/EEC will be transposed.

### **A. Raw materials, non-ferrous metals, ferro alloy, cement, glass, ceramics, paper and wood, publishing industry**

A Law on Valuable Metal Objects is planned to be adopted in which the following legal acts will be incorporated: 51993PC0322 and 51994PC0267. The law is planned to be adopted in the last quarter of 2005.

It is planned to adopt the Law on Mineral Resources and to incorporate the directives: 85/337/EEC, amended with 97/11/EC, 96/61/EC, 2001/42/EC, 2003/4/EC, 2000/60/EC.

### **B. Chemical products and rubber**

Within this field it is planned to be issued the Law on Chemicals as well as bylaws originating from this law. In the Law on Chemical the following directives will be harmonised: Council Directive 67/548/EEC, Commission Directive 2001/59/EC.

In the Republic of Macedonia the new Rulebook on Pneumatics for Tractors and their Trailers ECE P 106/00 is planned to be enforced on 01/10/2005. It means that there is a legal base for harmonisation of the national regulations with the requirements of the stated Rulebook.

### **C. Machine engineering, electrics and consumption electronics**

Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (deadline 2005)

- Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments and Council Directive 93/68/EEC of 22 July 1993 amending 90/384/EEC (non-automatic weighing instruments), (deadline 2006).
- Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and Council Directive 92/31/EEC of 28 April 1992 amending Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility, Council Directive 93/68/EEC of 22 July 1993 amending Directive 89/392/EEC (machinery), (deadline 2005)

- Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment, (deadline 2006)
- Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (deadline 2005)
- European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts, (deadline 2005/2006)
- Directive 96/57/EC of the European Parliament and of the Council of 3 September 1996 on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof, (deadline 2005/2006)

#### **D. Information technology industry**

- Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity, (deadline 2006)
- Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, (deadline 2005)

#### **E. Pressure vessels, medical devices, measuring instruments, medical devices, including active medical devices and test-tube instruments**

- Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot- water boilers fired with liquid or gaseous fuels, (deadline 2005/2006)
- Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels and Council Directive 90/488/EEC of 17 September 1990 amending Directive 87/404/EEC on the harmonization of the laws of the Member States relating to simple pressure vessels, Council Directive 93/68/EEC of 22 July 1993 amending Directive 87/404/EEC (simple pressure vessels), (deadline 2005/2006)
- Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels and Council Directive 93/68/EEC of 22 July 1993 amending Directive 90/396/EEC (appliances burning gaseous fuels), (deadline 2005/2006)
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, (deadline 2005/2006)
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, (deadline 2005/2006)

#### **F. Civil engineering and construction products**

- The Law on Construction with accompanying bylaws are in their final phase of preparation, and their adoption is expected in 2005.
- The preparation of the Law on Building Materials and Bylaws will begin in 2005, and their adoption is expected in 2006. These legal acts will be completely harmonised with the requirements of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products.

#### **G. Transport Equipment Industry**

- Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, (deadline 2006)

## H. Foodstuffs

- European Parliament and Council Directive 94/34/EC of 30 June 1994 amending Directive 89/107/EEC on the approximation of the laws of Member States concerning food additives authorized for use in foodstuffs intended for human consumption, (deadline 2005/2006)
- European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs, (deadline 2005/2006)
- Commission Regulation (EC) No 2/95 of 3 January 1995 altering the basic amount of the import levies on syrups and certain other products in the sugar sector, (deadline 2005/2006)
- Council Regulation (Euroatom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency, (deadline 2005/2006)
- Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance.), (deadline 2005/2006)
- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food, (deadline 2005/2006)
- Council Regulation (EC) No 2375/2001 of 29 November 2001 amending Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance), (deadline 2005/2006)
- Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients, (deadline 2005-2006)
- Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production, (deadline 2005/2006)
- Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs, (deadline 2005/2006)
- Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs, (deadline 2005/2006)
- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (Text with EEA relevance), (deadline 2005/2006)
- Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, (deadline 2005/2006)
- Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs, (deadline 2005/2006)
- Commission Directive 2003/40/EC of 16 May 2003 establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters, (deadline 2005/2006)
- Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer, (deadline 2005/2006)
- Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, (deadline 2005/2006)
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, (deadline 2005/2006)

## I. Textile and clothing, leather, footwear, furniture, toys

- Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, (planned for 2005)
- Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer, (planned for 2005)

- Directive 96/74/EC of the European Parliament and of the Council of 16 December 1996 on textile names, (planned for 2005)
- Council Directive 73/44/EEC of 26 February 1973 on the approximation of the laws of the Member States relating to the quantitative analysis of ternary fibre mixtures, (planned for 2005)
- Directive 96/73/EC of the European Parliament and of the Council of 16 December 1996 on certain methods for the quantitative analysis of binary textile fibre mixtures, (planned for 2005)

## **J. Pharmaceutical Products**

### **1. Medical products for human use**

In 2004, in the field of medical products for human use it is planned to make amendments to the Law on Pharmaceutical Drugs, Supplementary Treatment Substances and Medical Devices ("Official Gazette of RM" No. 21/98).

### **2. Veterinary medical products**

A new Law on Veterinary Medicinal Products with Bylaws is planned to be issued in 2007, which will be approximated with the European Union Legislation.

## **B. Calibration, metrology, standards, testing, certification, conformity assessment, accreditation and market surveillance**

### **1. Please provide information on the relevant regimes for the products:**

**(The answer should be in two parts, to cover industry in general and each of the individual sectors listed in Chapter 15 of the questionnaire, section II)**

- a) short description and**
- b) further evolution.**

#### **a)**

The current metrological infrastructure is oriented towards legal metrology, i.e. verification of mass measurements has been inherited from the previous system and is entirely centralised In the Bureau of Metrology. Industrial metrology, where calibration is present up to a certain extent, is entirely decentralised and underdeveloped.

Conformity assessment for the type of measurements is carried out administratively according to the existing rulebook, while market surveillance, in accordance with Article 39 of the Metrology Law ("Official Gazette of RM" No. 55/2002), has been left to market inspection, while the Bureau of Metrology takes part only by expert surveillance.

The import of measuring instruments is regulated with item 2 of the Decision for classifying import and export goods ("Official Gazette of RM" No. 56/2004) according to the administrative procedure for obtaining a decision for entry into the Registry of the Bureau for Metrology pursuant to the Draft Rulebook on the form, contents and way in which the Bureau for Metrology (hereinafter: the Bureau) maintains the Registry for entry of labels and certificates for conformity of the types of measurements, labels and brands, i.e. certificates for verification of foreign measurements, as well as on the form and contents of the decision for entry in the Registry, i.e. the decision denying entry in the Registry. In addition to the imported ones, the Registry of the Metrology Bureau also records the decisions for conformity assessment of the measuring instruments manufactured in the country. Pending the adoption of this Rulebook, the Bureau for Metrology carries out the import of measuring instruments under the D2 regime of the quoted Decision in accordance with the existing Rulebook on issuing confirmation for meeting metrological and other requirements for measurements.

**b) Future evolution**

The EU technical assistance with the CARDS/SMAQV'a project - Technical Assistance to the Institutes of Standardisation, Accreditation, Metrology and Quality Validation will provide the necessary standards to ensure monitoring and calibration for eight categories of measurements in 2005, as follows: mass, length, volume, pressure, electrical measures, time and frequency, thermometry, reference materials and control of packaged products. The arrangement of the laboratory premises for these standards is underway. The short-term national infrastructure development programme will establish national standards on mass, temperature and pressure by the end of 2006. This programme provides adoption of basic technical regulations on the implementation of the Metrology Law in 2005, which is in its draft version and has been developed in cooperation with international experts from the abovementioned CARDS/SMAQV'a project. Registration of the bodies for conformity assessment and adequate labelling of measurements is incorporated in this regulation and it will become mandatory following the signing of the document for the entry of Macedonia in EU.

The Directive 90/384/EEC on non-automatic weighing instruments is in the procedure of transposition in the national legislation with the technical assistance from GTZ within the project-Transposition of New Approach Directives in the National Legislation. The transposition of this directive requires acceptance of the European standard EN 45501 on the part of ISRM. The directives on packaged products will also be transposed with German technical assistance by the end of 2005.

See also answer to question [01 II B 1](#) of the same chapter.

### III. FOOD LEGISLATION

#### *A. Competent authority/ies*

**1. Provide flowcharts/organigrammes outlining levels of competencies and showing management lines to describe the structure and organisation of the services in charge of food safety. The division of competencies and the links between the central, regional and local levels should appear clearly (degree of decentralisation/devolution of competence should be defined).**

**Please describe the current status and the foreseen evolution with a precise timetable.**

With respect to foodstuffs, the competent authorities are the Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy. The activities of these ministries are carried out through operative offices:

- Expert offices taking part in planning and monitoring the situation in the field of foodstuff safety, as well as in developing regulations;
- Inspection services;
- Authorised expert organisations for laboratory control;
- Authorised expert organisations for education on minimum hygiene requirements.

Within these ministries there are bodies supervising the application of national regulations regarding issues related to food in a broader context:

- Ministry of Health – State Sanitary and Health Inspectorate (until 31.12.2004, and Food Directorate from 1.1.2005)
- Ministry of Agriculture, Forestry and Water Economy – the Veterinary Directorate, the Plants Protection Administration and the State Agriculture Inspectorate.

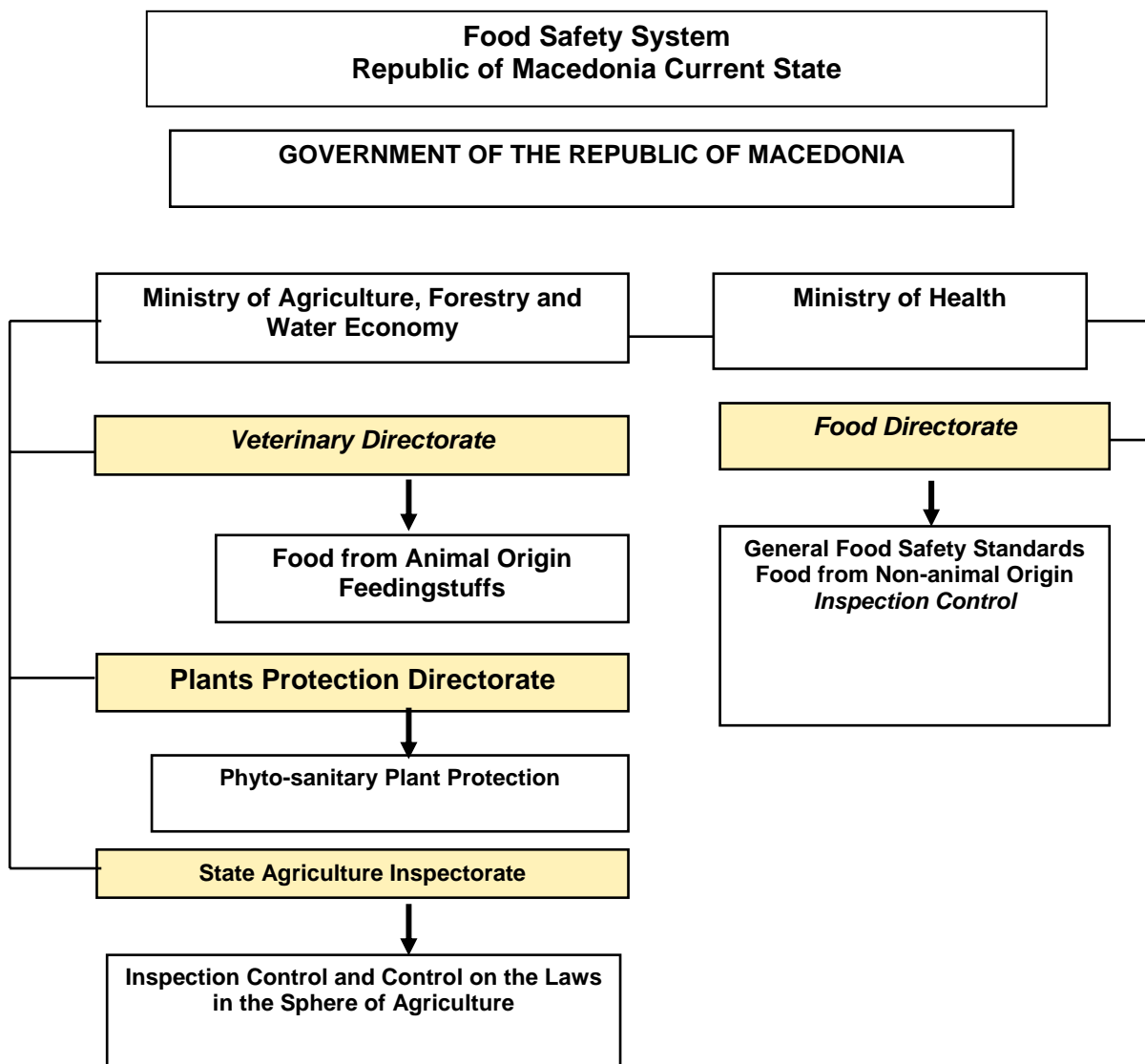
With the adoption of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) a Food Directorate has been established as a body within the Ministry of Health, while the control of foodstuffs and food related materials is carried out by foodstuff inspectors. The State Sanitary and Health Inspectorate and the State Market Inspectorate continue to carry out inspection supervision operations for food products and consumer goods pending the commencement of inspection supervision by the Food Directorate (01.01.2005), in accordance with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02)

Laboratory control is carried out in authorised institutions:

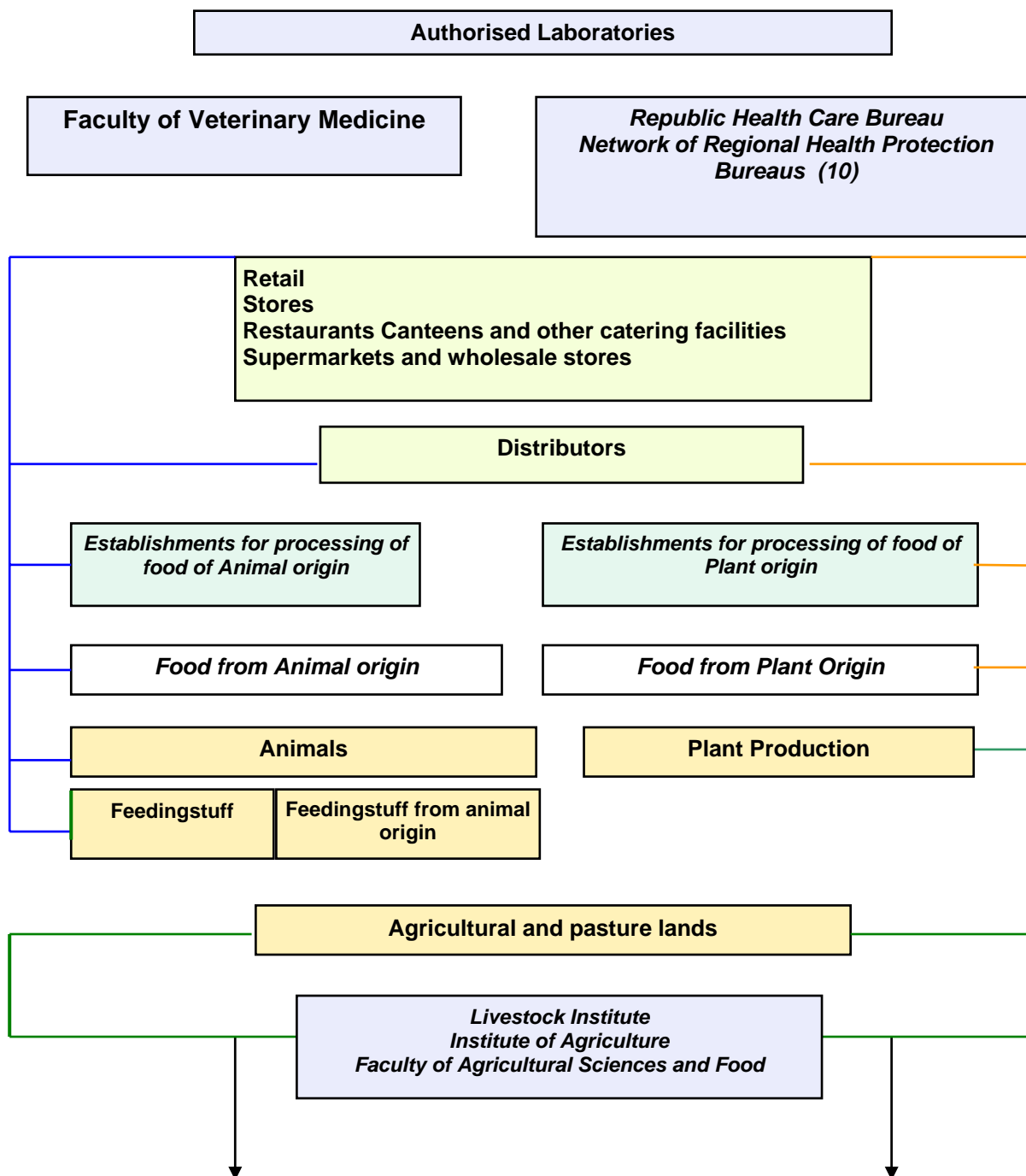
- the State Healthcare Institute;
- the Faculty of Veterinary Medicine;
- the ten regional healthcare institutes.

The organization chart of bodies competent for carrying out foodstuff safety control is given in Figure 1.

Figure 1







The Food Directorate, within the Ministry of Health, started to operate on 01.01.2005 in accordance with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02). With the adoption of this Law and the commencement of work of the Food Directorate the primary objective of the public healthcare policy in the field of foodstuff shall be achieved, upon which the four primary pillars of public healthcare are based: foodstuff safety, foodstuff adequacy, social justice and health ecology.

The adoption of regulations arising from the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) shall create conditions for establishing an integrated food control system in accordance with international standards and EU legislation in this field, thus transforming the traditional national system of foodstuff control into a modern system enabling prevention of food related diseases and injuries.

The competent institution for foodstuff safety and quality will be the Food Directorate, which, according to its organizational setup and statutory obligations, is provided to be competent for general requirements for foodstuff safety and special requirements for separate types of foodstuffs. Within the Directorate, inspection supervision is carried out through regional departments controlling food in specifically determined areas and through a single inspection supervision department competent for import and export foodstuff control. Official control will be carried out at all stages of the foodstuff chain by paperwork inspection, self-control inspection and taking samples. Foodstuff safety accountability is reduced to the food operator (producer). The timely and complete implementation of this system requires additional training for foodstuff inspectors, as well as for system operators of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and the HACCP procedures.

The Food Directorate has been incorporated in the National Strategy for Integrated Border Management and in the Action Plan for Integrated Border Management in the Republic of Macedonia. The activities of the Food Directorate in integrated border management started on 01.01.2005.

As regards food of animal origin, there is a detailed description in the answer to question [07 VII A 1.](#)

**2. Please indicate resources (human, material and financial) allocated to each sector. Please describe the current status and the foreseen evolution with a precise timetable.**

**Human resources:**

The State Sanitary and Health Inspectorate (hereinafter: SSHI) comprises - Directorate of the State Sanitary and Health Inspectorate, two Sectors and 19 regional units, established with the Rulebook on the Systematisation of Posts in the Ministry of Health.

The Expert and Operative Matters Sector manages the regional units of the State Sanitary and Health Inspectorate, as well as the Border Supervision Department. The Expert and Operative Matters Sector and the regional units assigned to the municipalities in the Republic of Macedonia are responsible for the sanitary safety of foodstuff in production and circulation in the Republic of Macedonia.

SSHI employees are part of the state administration, i.e. they hold the status of civil servants (counsellor – inspector) and are accountable for their work to the director, the sector manager and the department manager. In terms of education, they are doctors of medicine and doctors who specialise in preventive medicine. SSHI manages inspection supervision centrally, and it is organised in regional departments for a given geographic area. SSHI supervises the application of regulations in the field of controlling food, water, infectious diseases, beauty products, poisons, hospital hygiene, radiation safety, toys, tobacco and tobacco products, air pollution and noise.

The State Sanitary and Health Inspectorate employs a total of 95 inspectors.

Inspectors prepare monthly reports on their work and deliver them to the sectors of the State Sanitary and Health Inspectorate where reported data is gathered and analysed.

The Border Supervision Unit of the State Sanitary and Health Inspectorate is in charge of the supervision of sanitary safety of food imported into the Republic of Macedonia, and the supervision is carried out by state sanitary and health inspectors for border supervision at customs terminals and public customs warehouses on the territory of the Republic of Macedonia.

State sanitary and health inspectors for border supervision are organised into 11 centres in the Republic of Macedonia within 17 executive officers.

### Material resources

Salaries and other financial means for carrying out the regular activities and work of the SSHI are provided from the Budget of the Republic of Macedonia and are planned annually, which is coordinated by the Ministry of Health. A minor portion of the funds are provided from services, as given in the following table.

Data for 2003 MKD	
Total revenue:	Budget funds:
Budget funds:	41,257,000.00
For salaries, contributions and reimbursements:	26,591,000.00
Funds for reconstruction, equipment etc.	8,146,000.00
Own revenue:	14,200,000.00
Source: Ministry of Health, SSHI	

The State Healthcare Institute is a public healthcare organisation for high-quality specialised preventive healthcare in the Republic Macedonia.

The function of the State Healthcare Institute is carried out through different activities in the field of: epidemiology, hygiene, social medicine and modern laboratory research in the field of microbiology, toxicological chemistry, radio and bio-ecology and radio and bio-dosimetry. The State Healthcare Institute coordinates the activity of regional healthcare institutes, thus ensuring coverage of the entire territory of the Republic with the implementation of the unique and standardized measures and activities significant for public health protection.

The Sector for Hygiene and Protection of the Human Environment within the State Healthcare Institute is a link in the process of carrying out the national policy in the field of preventive medicine and, primarily, of healthcare and ecology in the Republic, as well as in the field of managing problems in the field of protecting human living and working environment, one of which is foodstuff. The Sector has laboratories for the purpose of establishing the sanitary safety of foodstuff, food and water related products; and the work in the Sector, in addition to laboratory tests, includes monitoring, assessment, proposed prevention measures and correction of potentially hazardous food polluting matter. Sector experts are included in the specialist training of medical staff and they take part in training people for individual analysis; they work on developing methods for food analysis; on proposing measures, legislation and secondary legislation acts in the field of food safety; and on preventing and fighting food-transmitted diseases, along with the other Sectors in the Institute and the State Sanitary and Healthcare Inspectorate.

The State Healthcare Institute is included in the development of the annual programmes for preventive healthcare along with the Ministry of Health. The State Healthcare Institute performs expert activities in the field of radio and bio-ecology and programme analysis of the sanitary safety of foodstuffs and consumption goods, as well as programmes monitoring of the alimentary daily input of chemical contaminants. The laboratory segment of these activities is fully carried out in the laboratories of the State Healthcare Institute.

The competencies of the State Sanitary and Healthcare Inspectorate are undertaken by the Food Directorate on 01.01.2005 as far as control of the sanitary safety of foodstuff and food related products and materials is concerned. All such activities are undertaken by the Food Directorate,

under the Organisation and Systematisation Act (based on the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02)

– Human resources

The Food Directorate consists of a director, 3 sectors and 12 departments. The total number of executive officers in the Directorate will be 75 with a projection of 15 new job positions. Sixty inspectors of the above number will come from the State Sanitary and Healthcare Inspectorate, who are doctors of medicine, and specialists in hygiene and epidemiology. Fifteen persons will come from the Ministry of Economy – the State Market Inspectorate, who are graduates from the Faculty of Technology (Foodstuff Department), the Faculty of Veterinary Medicine (doctors of veterinary medicine), biologists and agricultural engineers. Taking into account the multidisciplinary approach of foodstuff control and foodstuff risk analysis, 15 more job positions are projected in the Food Directorate.

- Material resources

Part of the office space in the regional departments will be transferred from the State Sanitary and Healthcare Inspectorate. The Budget Programme for 2005, projects funding for refurbishing offices at the central level and in regional department, including furniture, telephone lines and computer equipment with network connections. There is a need for additional financial support for establishing an appropriate IT system, as well as a need for appropriate system operator training. The amended budget projects funds are allocated for this proposes.

Salaries and other financial means for carrying out the regular activities and work of the Food Directorate are provided from the Budget of the Republic of Macedonia and are planned annually, which is coordinated by the Ministry of Health. A minor part of the funds are going to be provided from services at the request of applicants. The following table presents the proposed budget funds projected for the Food Directorate for the current 2005.

Proposed 2005 Budget MKD	
Total revenue:	Budget funds:
Budget funds:	71,772,000.00
For salaries, contributions and reimbursements:	31,330,000.00
Goods, services etc.	10,402,000.00
Funds for reconstruction, equipment etc.	30,070,000.00
Own revenue:	12,500,000.00
Source: Ministry of Health, Food Directorate	

**3. Please describe the current structure as well as the evolution foreseen. We would like to see two sets of organigrammes: one with the current structure and another one with the planned future structure (the dates foreseen for the establishment of new entities should be indicated).**

**Please describe the current status and the foreseen evolution with a precise timetable.**

The responsibility for foodstuff safety, from the independence of the Republic of Macedonia, lies with the Ministry of Health, the Ministry of Agriculture, Forestry and Water Economy, involved in various activities from the point of view of legislation, management, inspection, sampling, laboratory examination and proving food safety.

Within the Ministry of Health there is a Sector for Primary and Preventive Healthcare, which includes a Food Department with a mandate to develop and monitor healthcare policies related to food safety.

The Law on Sanitary and Health Inspection ("Official Gazette of RM" No. 19/95) regulates the work, composition, operation, authorisations and duties of state sanitary and healthcare inspectors, as well as the terms for carrying out professional tasks and the appointment of state sanitary and healthcare inspectors. According to the mentioned law, inspection supervision covers supervision of the

production and circulation of foodstuffs, drinking water, supervision of meeting sanitary and technical, and hygiene requirements for buildings, rooms, devices and equipment used in food production and trade, catering, buildings and devices used in drinking water supply, and etc.

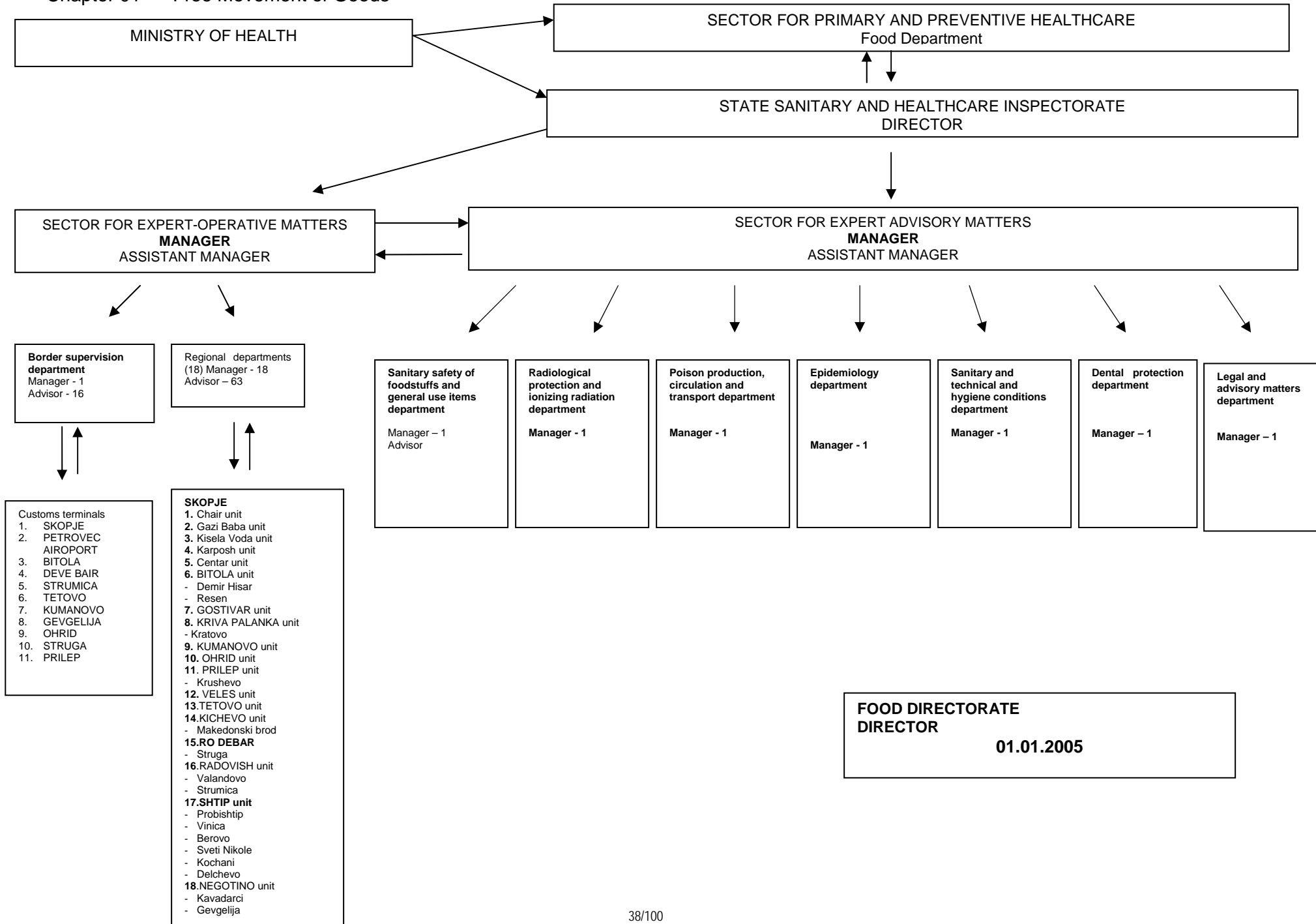
Inspection supervision also encompasses supervision of people who come in immediate contact with foodstuffs and drinking water, which can potentially jeopardize public health.

The competencies of the state sanitary and healthcare inspectors in controlling the safety of all types of food intended for human consumption were prescribed with the Law on the Sanitary Safety of Foodstuffs and General Use Items (Official Gazette of SFRY No. 53/91). With the adoption of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02), the provisions of the Law on the Sanitary Safety of Foodstuffs and General Use Items (Official Gazette of SFRY No. 53/91) shall cease, which relate to foodstuffs, vessels, utensils, plants and devices for producing and circulating foodstuffs and items in contact with foodstuffs, foodstuffs packaging, tobacco, tobacco products and smoking equipment.

The State Sanitary and Healthcare Inspectorate consists of – the director of the State Sanitary and Healthcare Inspectorate, two sectors and 19 departments.

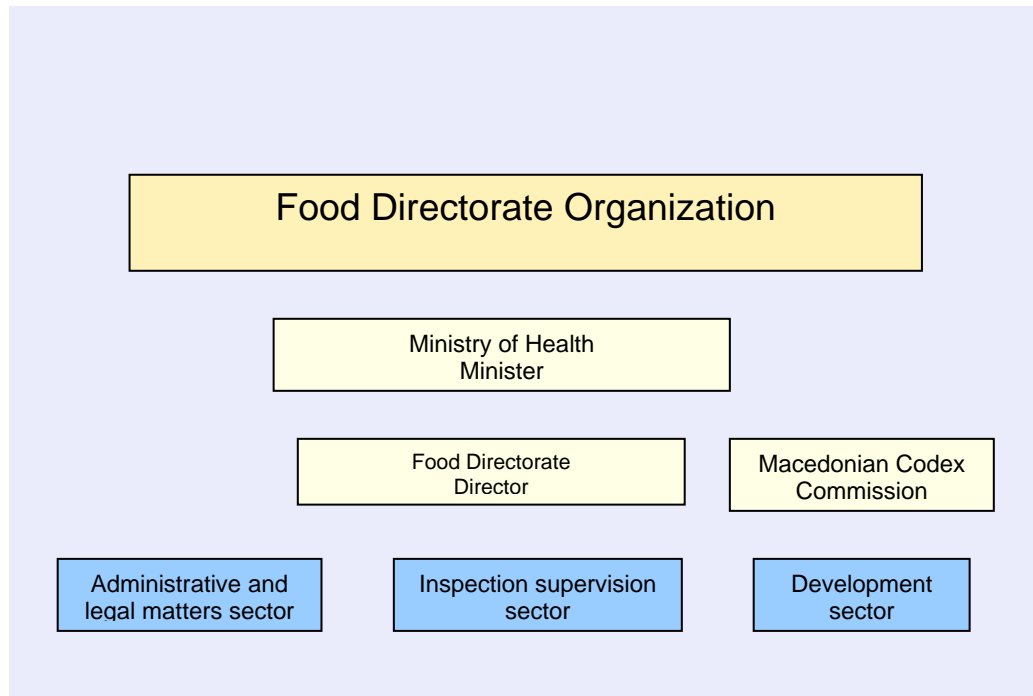
The Public Healthcare Institution - State Healthcare Institute and the Faculty of Veterinary Medicine are expert institutions – laboratories, authorised by the Minister of Health to carry out laboratory research. The establishment of the Food Directorate facilitated the conditions for improving the strategic management of foodstuff safety, and food contact products and materials, based upon, *inter alia*, the risk assessment.

## Chapter 01 Free Movement of Goods

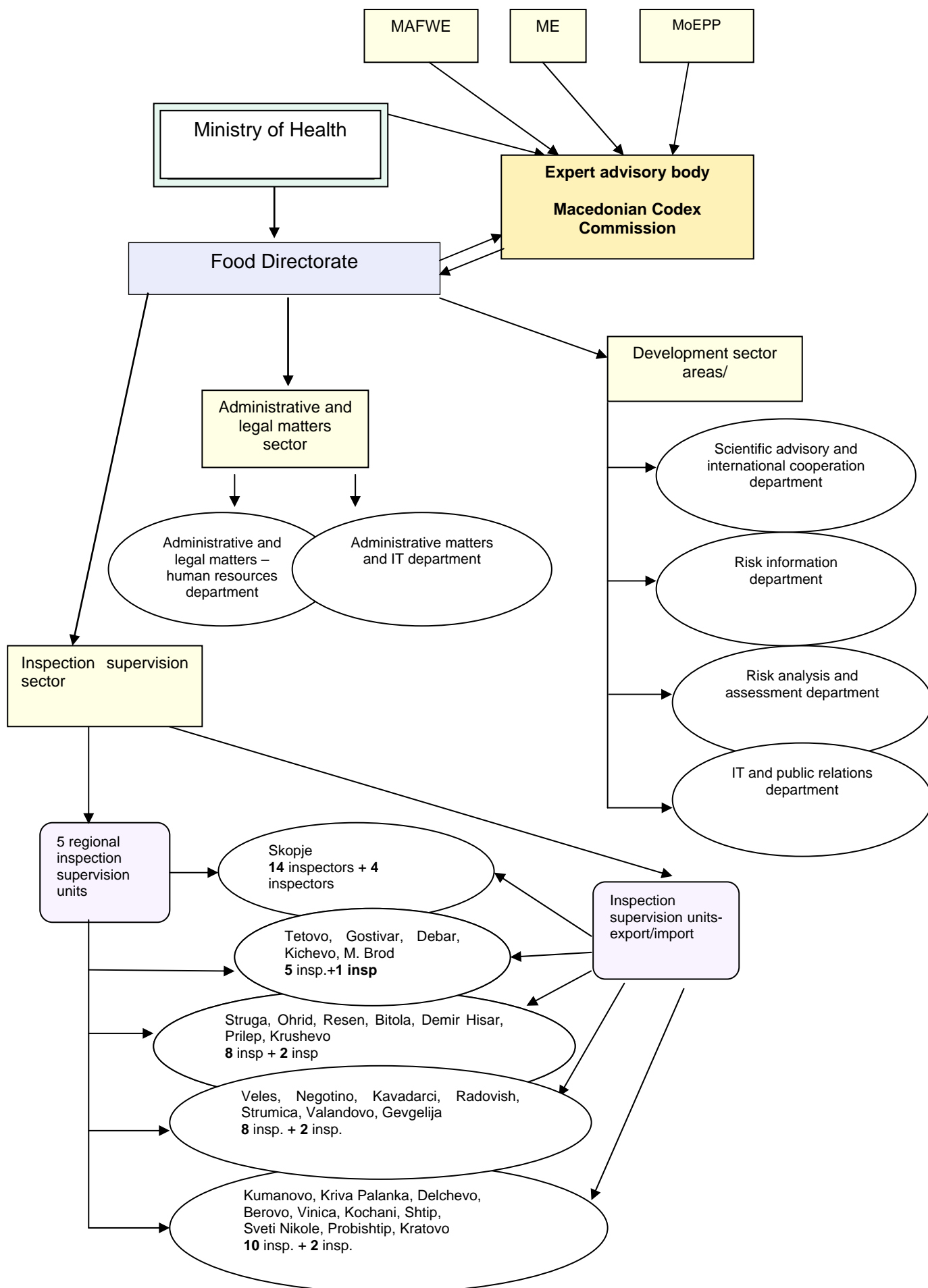


By undertaking the activities of the State Sanitary and Healthcare Inspectorate, the Food Directorate, taking into account the interests of the consumers and the industry, enabled enforcement of the food safety policy addressing key issues and hazard prevention.

No. A: 3/1



## Organisation Chart A: 3/1





Source: Ministry of Health, Food Directorate

The Food Directorate shall publish expert and administrative matters related to food of non-animal origin and it will be accountable for its work before the Minister of Health.

The Food Directorate as a new body within the Ministry of Health is a central authority in charge of inspection and supervision of the entire foodstuff chain. The main objective is to undertake steps to guarantee that the foodstuffs produced, distributed or labelled in the country are in conformity with the highest foodstuff safety and hygiene standards, as well as to guarantee that the foodstuffs are in conformity with the legal requirements and that they are consistent with the codes of good stuff practice.

In addition to official control of foodstuff safety, the Food Directorate participates in the development of regulations in the field of food, it organises inspector education, develops guides for good production practices, good laboratory practices, guides for applying the HACCP system, etc.

The Food Directorate forwards all information related to foodstuff hazards and it establishes coordination of the information system with other services involved in this field.

The Food Directorate started to operate as a body on 1.01.2005. The primary programme objective of the Food Directorate is the protection of consumer health and protection from misguidance by establishing a new institutional system for carrying out expert and administrative matters in the field of food safety, as well as by reforming the food control system in accordance with EU legislation and by observing the WTO membership commitments.

In addition to carrying out safety control (ingredients, contaminants, microbiological safety), the Directorate shall undertake the previous activities of the Ministry of Economy concerning quality control of foodstuffs, which includes quality analysis (ingredients, label conformity). Thus, the overlapping of control in both ministries will be disabled, costs will be reduced and proper regular food control procedures shall be established.

Control of food of animal origin is within the competence of the Veterinary Administration within the Ministry of Agriculture, Forestry and Water Economy. The Food Directorate, as a competent food control body in the Republic of Macedonia, shall coordinate all activities with the Veterinary Administration as regards the monitoring the quality and safety control of food. The competence of the Food Directorate covers several aspects of implementing a food safety policy in accordance with WTO, gathering and analyzing data as a basis for undertaking measures for transparent information and consumer protection. According to EU regulations, this Directorate analyses data and information from other relevant institutions and it performs full data analysis, enabling identification and monitoring of risks with direct or indirect influence on the safety of products (in accordance with Regulations 178/2002/EC, 882/2004/EC and 852/2004/EC).

Cooperation and coordination between the Ministries also takes place through the scientific advisory inter-ministerial body (Macedonian Codex Commission - MCC) and through the committees working within the Food Directorate.

The inclusion of the Macedonian Consumer Association will enable immediate involvement of consumer requirements for quality and safety. However, in addition to this, the Directorate has a coordination, communication and promotion department, enabling transparent communication of information to the Government, consumers and the international community.

There are 3 sectors with 12 units within the Directorate, as follows:

#### **Administrative and legal matters sector**

The administrative and legal matters sector carries out normative and legal issues, and expert work for performing the primary activity of the Food Directorate, human resources, as well as for the work of the IT analytic system for logistic support of the overall work.

**The administrative and legal matters, and human resources unit** prepares regulations within the competence of the Food Directorate, develops guides for inspection supervision, good production practices, good hygiene practices, the HACCP system, good laboratory practices, monitoring application of regulations and other secondary legislation acts within the competence of the Directorate, it develops a strategy for training foodstuff inspectors and keeping records of the training and other activities.

**The administrative matters and IT unit** carries out normative and legal, and expert work for performing the primary activity of the Food Directorate, human resources, as well as for the work of the IT analytic system for logistic support of the overall work.

### **Inspection supervision sector**

The Inspection supervision sector carries out the work and tasks concerning control of foodstuff and products and materials in contact with foodstuffs, through monitoring the implementation of regulations in the field of food of non-animal origin.

The inspection supervision units carry out the work and tasks concerning:

**Unit 1** carries out inspection supervision in the area of the city of Skopje with its municipalities.

**Unit 2** carries out inspection supervision in the area of the municipalities: Tetovo, Gostivar, Debar, Kichevo and Makedonski Brod;

**Unit 3** carries out inspection supervision in the area of the municipalities: Struga, Ohrid, Resen, Bitola, Demir Hisar, Prilep and Krushevo;

**Unit 4** carries out inspection supervision in the area of the municipalities: Veles, Negotino, Kavadarci, Radovish, Strumica, Valandovo and Gevgelija;

**Unit 5** carries out inspection supervision in the area of the municipalities: Kumanovo, Kriva Palanka, Delchevo, Berovo, Vinica, Kochani, Shtip, Sveti Nikole, Probishtip and Kratovo.

**Import and export, inspection supervision unit** carry out the work and tasks concerning: control of food and products and materials in contact with foodstuffs in import and export.

### **Development sector**

This sector carries out identification, analysis, assessment and communication of risk with regard to the sanitary safety of foodstuffs for the purpose of timely prevention of all potential hazards, as well as for applying scientific knowledge regarding foodstuff safety and enabling international cooperation of interest for the work of the Food Directorate.

**The scientific advisory matters and international cooperation unit** ensures the consistency of procedures for developing scientific opinions, develops procedures for harmonizing working methods, on the basis of opinions of scientific committees, it prepares expert and scientific view on various types of foodstuff as potential risks to human health, issues opinions and approvals for producing foodstuff with special nutrition use and food produced with innovative technology, as well as foodstuffs produced by using ionizing radiation, creates an information exchange facility for potential risks, proposes a foodstuff safety policy in accordance with WTO, follows all EU information related to foodstuff safety, undertakes measures for establishing international cooperation with institutions and organisations dealing with food and diet, FAO, WHO, WTO etc.

**The risk assessment and analysis unit** undertakes activities of coordinated operation together with the Ministry of Agriculture, Forestry and Water Economy related to foodstuff safety control, as well as development and design of regulations in the field of foodstuffs, prepares potential risk analyses of the data obtained from other competent inspection bodies, monitors risks, develops a crisis management plan, provides suggestions for promoting the process of risk assessment by regions.

**The risk information unit** undertakes measures for transparent consumer information and protection, establishes an early warning system and forwards information related to food hazards, and it presents a central data exchange body concerning crises. A Rapid Alert System for Food and Feed (RASFF) will be established in the same unit.

**The IT and public relations unit** manages the database of all the data, keeps a registry of all foodstuff manufacturing and processing facilities, distribution centres and catering facilities. It develops publications and other informative material intended for the public and related to the work of the Directorate, it develops and maintains a web page of the Directorate, and communicates with the public and provides information regarding key changes in the legislation, technique and operation in the Directorate.

## ***B. Legislative powers for food legislation***

**1. Please specify the competent authorities (for legislation) and how legislation is (or will be) passed (primarily through parliamentary procedure or ministerial orders or decrees). Please describe the current status and the foreseen evolution with a precise timetable.**

The Assembly of Republic of Macedonia is the highest state institution for adopting laws. Each member of the Parliament, the Government of the Republic of Macedonia and at least 10.000 electors are entitled to propose adoption of a law (authorised law drafters). Carriers of law drafting procedure are the competent administrative authorities.

The Assembly shall adopt laws by majority of votes from the present members of Parliament, and at least with a third of the total number of MPs, unless a special majority is provided by the Constitution.

Following adoption, laws are published in the Official Gazette of RM.

Secondary legislation (rule books, orders, decisions) in certain areas, for whose adoption there is legal basis in an appropriate *lex generalis*, are adopted on the part of the competent minister on the basis of relevant laws.

Such secondary legislation must previously be approved by the Legislation Secretariat that they are in conformity with the Constitution of Republic of Macedonia and other legal regulations. Following adoption secondary legislation is published in the Official Gazette of RM.

Legislation in force in the field of healthcare

- Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs (“Official Gazette of RM” 54/02)

Secondary legislation to be adopted on the basis of the aforementioned law is in preparation, and the technical regulations on food, taken from the SFRY legal system are in force. The Macedonian Food Code shall consist of all food regulations to be adopted on the basis of the above law.

In the strategic objective of the Food Directorate evaluation of Food legislation in the Republic of Macedonia is foreseen, as well as adoption of secondary legislation harmonised in accordance with the regulations of the European Union by December 2005. ([01 III D 2](#))

**2. Please explain how co-ordination is (or will be) ensured in terms of transposition, implementation and policy-making to ensure that the food chain is fully covered. Please describe the current status and the foreseen evolution with a precise timetable.**

The Law on Organisation and Operation of the State Administrative Bodies (“Official Gazette of RM” No. 58/00 and 44/02) provides an obligation of the state administration bodies carrying out inspection work, to cooperate in carrying out inspection work among each other, as well as with other state administration bodies, i.e. if a mistake is established in the course of the inspection supervision, they are obliged to notify the appropriate authority, i.e. the inspection service in order to undertake adequate measures within their authorisations.

The Ministry of Health carries out the work related to foodstuff safety, while the Ministry of Agriculture, Forestry and Water Economy– Veterinary Administration carries out the work related to food of animal origin, in accordance with the regulations on veterinary healthcare and the general requirements provided in the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs (“Official Gazette of RM” 54/02)stuff and Food Contact Products and Materials (“Official Gazette of RM” No. 54/00).

The control of primary plant production from the viewpoint of foodstuff safety is provided in the answer to questions [07 VII A 1](#) and [07 VII A 3](#).

The enforcement of the provisions of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs (“Official Gazette of RM” 54/02) from the viewpoint of foodstuff safety were carried out by the State Sanitary and Health Inspectorate within the Ministry of Health, and starting from 1.01.2005 all competencies are undertaken by the Food Directorate.

The Macedonian Foodstuff Code consists of all regulations on foodstuffs that are produced and put into circulation in the Republic of Macedonia. For the Macedonian Foodstuff Code the Minister of health established a Commission in October 2004 as an expert advisory body comprising representatives of the Ministry of Health, the Ministry of Agriculture, Forestry and Water Economy, the Ministry of Economy and the Ministry of Environment and Physical Planning, upon the proposal of the competent ministers and eminent scientific and expert associates and representatives of the consumer association. The commission considers the issues regulated by the Macedonian Foodstuff Code as well as the methods of foodstuff analysis based on international scientific achievements, and provides recommendations in its field of work, based on the recommendations of international organisations harmonised with the requirements and conditions in the country. Eight committees consisting of experts in relevant fields work within the Directorate. On the basis of the data obtained by control or from the foodstuff risk warning system of another country in the region and wider, a special programme shall be developed by the experts for protection from the respective risk and for possibilities for removing it if present in our country. The committees are in charge of providing scientific opinions to the Directorate, each within its domain, and when public debates need to be organised.

The science committee are in charge of the general coordination necessary to ensure consistency of the procedures for developing scientific opinions, as well as, in particular, with respect to the adoption of working procedures and working methods harmonisation.

In April 2004 the Government of the Republic of Macedonia adopted the Food and Diet Action Plan. The development of the priorities of the Food and Diet Action Plan of the country is based on the three pillars of the food and diet policy: diet strategy, safe food strategy and appropriate food supply strategy, as a priority in preventing food and diet related diseases, as well as on the commitments of the Republic of Macedonia as a member country of the World Health Organisation. The Food and Diet Action Plan is a result of a multi-sector approach accomplished through the work of the National Food and Diet Committee, which, though nominated by the Minister of health, includes representatives of the Ministry of Agriculture, Forestry and Water Economy, the Ministry of Economy, representatives of the highest education institutions, the consumer association etc.

The following activities have been carried out in the area of transposition and implementation of the Codex Alimentarius standards into the national legislation:

- A National Codex Office has been established as a central authority for relations with the Codex Alimentarius Commission, with other member countries, and, in the country, with the relevant Ministries, the food industry, the consumers, the sellers and the interested organisations and individuals.
- A multi-sector National Food and Diet Committee and a Codex Alimentarius Committee has been established within the Ministry of Health, including representatives from the relevant ministries, the foodstuff industry, trade sector, science organisations, and consumer association.

The further development of the foodstuff safety system is carried toward approximation and full harmonisation of foodstuff safety legislation with EU law. The national programme for approximation of legislation envisages the directions and timeframes in this area.

### ***C. Control activities and enforcement in the field of food legislation***

**1. Please specify the competent authorities that are (or will be) in charge of control activities and enforcement and their respective responsibilities. Describe mechanisms of co-ordination when relevant. Please describe the current status and the foreseen evolution with a precise timetable.**

Competencies are clearly divided with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02). Starting from 01.01.2005 the competencies of the State Sanitary and Health Inspectorate are undertaken by the Food Directorate, which decides upon issues related to the supervision of the application of this regulation.

Until 31.12.2004, the State Sanitary and Health Inspectorate in Skopje coordinated the work of the sanitary and health inspectors with offices in the municipalities in the Republic of Macedonia, with a precisely designated geographic area of inspection. Furthermore, it processed monthly reports of the state sanitary and health inspectors from the regional units with regard to the foodstuff supervision carried out. It was obliged to notify them of all sanitary unsafe foodstuff findings and of the need for their withdrawal from circulation.

The work of the sanitary inspectors for border supervision is coordinated by the Ministry of Health where the office of the manager of the border supervision department of the State Sanitary and Health Inspectorate is located, and all inspectors receive procedure instructions for each issue within the scope of activities and relevant notifications also delivered.

The manager directly organises and focuses the work of the sanitary inspectors on the field. Feedback is delivered by regular monthly reports on the activities carried out.

The Food Directorate took these activities from the State Sanitary and Health Inspectorate within its competence from 01.01.2005 with the adopted acts for organisational setup and systematisation of posts in the Food Directorate.

The control of foodstuffs and food contact products and materials, are carried out at all stages of production and circulation by the Food Directorate and its food inspectors in accordance with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) It covers raw materials, additives, subsidiary technological means and all other substances used in production.

1. semi-finished products or ready-made foodstuffs, regardless where they are produced or for which market they are intended;
2. products and materials that can come in contact with food;
3. cleaning procedures and means and DDD;
4. The condition and use of locations, buildings, rooms, offices, the plant surroundings, transport vehicles, machine devices and equipment at all stages of production and circulation;
5. The food production technological processes;
6. The packaging, marking, information and advertising, as well as presentation of foodstuffs and food contact products and materials;
7. The HACCP in production or the foodstuff trader;
8. The methods and ways of foodstuff preservation;
9. The hygiene and health condition of the persons coming in direct or indirect contact with materials and food.

The Law provides that inspection supervision shall be carried out regularly, and systematically according to an established plan, and in the event of doubt. Inspection supervision shall be carried out without prior notification. When carrying out inspection supervision the inspector shall, as a rule,

select the stage or stages of each separate segment that they deem most suitable for carrying out supervision.

Such supervision shall cover one or more of the following inspection procedures:

1. General inspection of documents;
2. Taking samples for laboratory analyses and examinations;
3. Inspection of staff hygiene;
4. Inspection and control of the HACCP verification system applied by the producer and trader and the results thereof;
5. Inspection and control of the values registered by measuring instruments of the producer and trader, and control by measuring instruments of the inspector.

The inspection supervision of foodstuff of animal origin is carried out by the Veterinary Directorate in accordance with the Food Lawstuff Safety and the regulations in the field of veterinary healthcare. A more detailed description is provided in the answer to question [07 VII A 5.](#)

The Food Directorate plans the following future activities:

- a) *Development of an early warning system for the relevant hazards by regions. Establishment and implementation of an analysis sector for information on food safety policy.* The key role of this department consists of enforcement and monitoring of the food safety policy and the development of a system for risk management, mapping potential threats and providing council in such situations. With regard to Regulation 882/2004/EC, in the event of existence of several competent institutions (the Veterinary Directorate, the Plant Protection Directorate and the State Agricultural Inspectorate within the Ministry of Agriculture, Forestry and Water Management, as well as the State Environment Inspectorate within the Ministry of Environment and Physical Planning) in order to implement efficient official control, efficient and expert coordination and cooperation between the departments will be established;
- b) *A programme for establishing and maintaining communication with all involved partners, including consumers. Establishing and maintaining an information system on the needs of the Food Directorate.* This system will enable the establishment of direct intranet connection with all regional food inspectors, including border inspection with the central directorate, as well as connection with authorized food laboratories, other inspectorates carrying out foodstuff control and the consumer associations;
- c) *Work on a commission for the Macedonian Foodstuff Code as an expert advisory body* – on the basis of intra-sector cooperation with representatives from the competent ministries and eminent scientists and professionals;
- d) *Establishment and active work of committees consisting of experts in certain fields, which are to prepare expert opinions on implementing a system for risk analysis and implementation of precautionary principles and accountability of all who deal with food and cattle feed.* In this way, thus adequate protection from potential risks to people's health will be ensured;
- e) Introduction of a registry of food production facilities in the Republic of Macedonia;
- f) *Issuing production approvals for foodstuffs with special nutrition use and foodstuffs produced with innovative technology, as well as foodstuffs produced by using ionising radiation;*
- g) Establishment and maintenance of a public relations office: regular communication with the public and providing information on certain fields with respect to key changes in politics, legal regulations, technology and institutions within the Directorate in accordance with government protocols, as well as communication with the public as regards complaints on the work of the Directorate or on the quality and safety of foodstuffs in production, transport and circulation.
- h) *A programme for taking samples which will precisely define the work of inspection services, the manner of taking samples, the number of samples depending on the risk degree, the type of the product, the capacity of the plant, and etc. in accordance with documented procedures*

*and legal obligations under EU regulations.* The controls carried out by the competent institution must be in accordance with documented procedures. Such procedures must contain information and instructions on staff actions in carrying out official control;

- i) *Developing an official control guide in accordance with EU procedures.* The guide shall contain recommendations for the official control of:
  - the implementation of the HACCP principles
  - the management systems that foodstuff business operators must implement in order to accomplish the requirements provided for in the Food Law
  - Microbiological, physical and chemical food safety.
- j) *A programme for upgrading and training inspectors* which will enable a completely new approach to foodstuff control in all segments of the food chain.
- k) *In 2005, in cooperation with the competent ministries, the activities for establishing an early warning system shall commence.*

#### ***D. Transposition and implementation of legislation***

**1. Describe transposition/implementation plans (including enforcement) with precise and detailed timetables and dates with reference to the individual piece of EU legislation transposed/implemented in the area of food legislation. In case of only partial compatibility with EU legislation it should be made clear which part of the legislation is compatible and when the other part will be aligned and implemented. Please describe the current status and the foreseen evolution with a precise timetable.**

Harmonisation of national legislation on the safety of foodstuffs and food contact products with EU legislation shall be carried out with technical assistance of the European Agency for Reconstruction and Development. The specification of transposition of directives with a precise schedule and deadlines is provided in the National Programme for Approximation of National Legislation to EU Legislation adopted by the Government of the Republic of Macedonia on 22.03.2004, as well as in the Action Plan for the European Partnership adopted in 2004.

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) regulates the conditions for ensuring the safety of foodstuffs and food contact products and materials, production and circulation, the rights and obligations of natural and legal persons producing or circulating, with the general objective to protect human health, and consumers from misguidance and enabling free circulation on the internal and external market.

The Law is in function of creating normative and legal and other prerequisites for establishing an integrated and efficient system for control of foodstuffs and food contact products and materials, as well as in the function of the associative processes with EU - WTO.

The Law shall ensure confidence with the consumer and protection from misguidance through adequate and timely information on food safety, as well as efficient supervision of production, import and circulation, and protection of consumer health.

The basis in the development of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) was the Regulation 178/2002/EC of the European Parliament and the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority.

The Law is normatively and technically designed to be internationally recognisable, with an approach for horizontal and vertical regulation (primary law and a large number of secondary legislation).



National legislation in the Republic of Macedonia in the field of foodstuff safety is based on the following EU regulations:

- Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 06.05.2000).
- Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs (OJ L 208, 24.07.1992)
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (OJ L 106 17.04.2001).
- Council Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24.11.1993),
- Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients (OJ L 043, 14.02.1997).

All EU directives and regulations that are not incorporated in the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) are going to be incorporated in secondary legislation which is in the stage of preparation. The Implementation of EU legislation is answered in question [01 III B 1](#) and [01 III B 2](#).

### **Secondary legislation in force:**

1. Rulebook on the conditions and the manner of examination of foodstuffs and consumer goods in the course of their production and on the way of keeping record of the examinations carried out (Official Gazette of SRM 20/76).
2. Rulebook on the methods of sampling and carrying out chemical and physical analysis of alcoholic beverages (Official Gazette of SFRY 70/87).
3. Rulebook on the methods of physical and chemical analysis for controlling the quality of wheat, mill and pastries, pasta and fast frozen pastries (Official Gazette of SFRY 74/88).
4. Rulebook on the methods of sampling and carrying out chemical and physical analysis of milk and dairy products (Official Gazette of SFRY 32/83).
5. Rulebook on the general minimum technical requirements for the rooms, devices and equipment for production, storage, keeping and circulation of foodstuffs and consumer goods (Official Gazette of SRM 17/79).
6. Rulebook on the methods of sampling and carrying out chemical and physical analysis for the control of the quality of fruit and vegetable products (Official Gazette of SFRY 29/83).
7. Rulebook on the methods of sampling and carrying out chemical and physical analysis of the quality of vinegar and diluted acetic acid (Official Gazette of SFRY 26/89).
8. Rulebook on the methods of sampling and carrying out chemical and physical analysis of protein products in the food industry (Official Gazette of SFRY 41/85).
9. Rulebook on the methods of sampling and carrying out chemical and physical analysis of cocoa grain, cocoa products, chocolate similar products, cream products, biscuits and biscuit related products. (Official Gazette of SFRY 41/87).
10. Rulebook on the conditions for microbiological safety which foodstuffs in circulation must meet (Official Gazette of SFRY 45/83, 43/89).
11. Rulebook on the conditions for sanitary safety of dieting foodstuffs that have to be placed in circulation (Official Gazette of SFRY 4/85, 70/86, 69/91).
12. Rulebook on the quantity of pesticides and other toxic material, hormones, antibiotics and micro-toxins which can be found in foodstuffs (Official Gazette of SFRY 59/83, 33/87, 79/87).
13. Rulebook on the conditions for sanitary safety of consumer goods that can be placed in circulation (Official Gazette of SFRY 26/83, 61/84, 56/86, 50/89, 18/91).
14. Rulebook on the conditions under which foodstuffs and consumer goods canned by radiation can be placed in circulation (Official Gazette of SFRY 68/54).
15. Rulebook on the conditions under which drinking water, foodstuffs and consumer goods containing radioactive material above certain activity levels can be placed in circulation (Official Gazette of SFRY 23/86).
16. Rulebook on the safety of drinking water ("Official Gazette of RM" No. 5/04).
17. Rulebook on the quality of natural mineral water (Official Gazette of SRM No. 58/78).
18. Rulebook on the method of determining and maintaining safety zones around drinking water springs (Official Gazette of SRM No. 17/83).



19. Regulation for water classification ("Official Gazette of RM" No. 18/99).
20. Regulation for water categorisation ("Official Gazette of RM" No. 18/99).
21. Decision on designating healthcare and other organisations for carrying out and examining the sanitary safety of foodstuffs and consumer goods (Official Gazette of SRM 27/81, 39/82, 15/91).
22. Decision on healthcare and other organisations that are in compliance with the conditions for super analyses of foodstuffs and consumer goods (Official Gazette of SFRY 68/91).
23. Decision on designating the places where sanitary supervision of foodstuffs and consumer goods can be carried out (Official Gazette of SFRY 85/91).
24. Guidelines for the method of delivering reports on the implementation of the Law on the Health Safety of Foodstuffs and Products for General Use and of the regulations adopted on the basis of that Law (Official Gazette of the SFRY 45/84).
25. Guidelines on the method of sampling for carrying out analyses and super analyses of foodstuffs and consumer goods (Official Gazette of SFRY 60/78).
26. Decree for labelling attested special equipment of transport vehicles for international transport and perishable foodstuffs (Official Gazette of SFRY 24/78).
27. Rulebook on the methods of designating pH values and the quantity of toxic metals and non-metals in personal hygiene, facial and body care and beauty products, and on establishing the microbiological safety of such products (Official Gazette of SFRY 46/83).
28. Decree for compulsory product specification on machine and manual laundry detergents for textile goods (Official Gazette of SFRY 53/83).
29. Decree for compulsory adoption of product specification for:
  - hair shampoos (Official Gazette of SFRY 29/85);
  - toothpaste (Official Gazette of SFRY 29/85);
  - Liquid detergents for manual dishwashing (Official Gazette of SFRY 67/85).
30. Decree for packaging and declaring:
  - hair shampoos (Official Gazette of SFRY 34/90);
  - washing powder for textile goods (Official Gazette of SFRY 53/83);
  - liquid detergents for manual dishwashing (Official Gazette of SFRY 34/90);
  - Toothpastes (Official Gazette of SFRY 29/85, 26/90).
31. Rulebooks on the quality of beverages:
  - Rulebook on the quality of wine (Official Gazette 17/81 and 14/89).
  - Rulebook on the quality of alcoholic beverages (Official Gazette 16/88 and 64/88).
  - Rulebook on the quality of alcoholic and non-alcoholic beverages, ice and vinegar (Official Gazette 31/63, 25/65, 45/71, 48/71, 25/75, 18/77, 13/78, 53/78, 2/82, 34/82, 52/83, 58/83, 16/88, 24/89 и 91/91).
  - Rulebook on the quality of refreshing non-alcoholic beverages (Official Gazette 52/83 and 56/83).
  - Rulebook on the quality of beer (Official Gazette 91/91).
  - Rulebook on the quality of natural mineral water (Official Gazette 57/78).
  - Rulebook on the methods of sampling and carrying out chemical and physical analysis of alcoholic beverages (Official Gazette 70/87).
32. Rulebooks on the quality of coffee and coffee substitutes:
  - Rulebook on the quality of coffee, coffee products and coffee substitutes (Official Gazette 55/89, 57/89 and 36/91).
  - Rulebook on the quality of coffee and coffee substitutes, tea, spices, baking yeast, baking powder, pudding powder, dieting products and additives (Official Gazette 22/63, 2/64, 25/65, 50/66, 10/67, 54/67, 15/78, 27/71, 8/75, 58/77, 60/77, 20/80, 41/80, 45/81, 52/86, 33/89 and 13/78).
33. Rulebooks on the quality of wheat and baking products:
  - Rulebook on the quality of wheat, mill and baking products, pastries and fast frozen pastries (Official Gazette 53/83 and 57/88).
  - Rulebook on the quality of baking yeast (Official Gazette 32/87).
  - Rulebook on the quality of biscuits and biscuit related products (Official Gazette 68/78 and 63/79).

- Rulebook on the methods of physical and chemical analyses for controlling the quality of wheat, mill and baking products, pastries and fast frozen pastries (Official Gazette 74/88).
  - Decree on the method of grinding wheat (Official Gazette 62/82 and 50/81).
  - Rulebook on the methods of taking samples and carrying out chemical and physical analysis of cocoa beans, cocoa products, chocolate similar products, bonbon products, cream products, biscuits and biscuit related products (Official Gazette 41/87).
34. Rulebooks on the quality of food industry proteins:
- Rulebook on the quality of protein products and mixtures of protein products for food industry (Official Gazette 41/85).
35. Rulebooks on the quality of edible fats:
- Rulebook on the quality of fat and vegetable fat, margarine, mayonnaise, sugar and other saccharine, candy products, honey, cocoa products and products similar to chocolate (Official Gazette 19/63, 2/64, 27/71, 54/76, 59/77 and 13/78).
  - Rulebook on the quality of edible and vegetable fats, and margarine, mayonnaise and similar products similar (Official Gazette 27/85 and 51/91).
  - Rulebook on the quality of olive oil and mixed olive oil (Official Gazette 51/91).
36. Rulebooks on the quality of milk and dairy products:
- Rulebook on the quality of milk, dairy products, thick milk and pure cultures (Official Gazette 51/82 and 39/89).
  - Rulebook on the methods of sampling and carrying out chemical and physical analysis of milk and dairy products (Official Gazette 32/83).
37. Rulebooks on the quality of eggs and egg products:
- Rulebook on the quality of eggs and egg products (Official Gazette No. 55/89).
  - Rulebook on the methods for examining the quality of eggs and egg products (Official Gazette 72/87).
38. Rulebook on the quality of honey and other bee products and on the methods of controlling the quality of honey and other bee products (Official Gazette 4/85).
39. Rulebook on the quality of foodstuffs additives (Official Gazette 39/89 and 22/90).
40. Rulebooks on the quality of cocoa and cocoa products:
- Rulebook on the quality of cocoa products, products similar to chocolate, cream products and bonbon products (Official Gazette 23/88, 63/88, 36/89 and 21/90).
  - Rulebook on the methods of taking sampling extracts and carrying out chemical and physical analysis of cocoa beans, cocoa products.
  - Rulebook on the methods of taking sampling extracts of food industry protein products (Official Gazette of SFRY 41/85).
41. Rulebooks on the quality of meat and meat products:
- Rulebook on the quality of slaughtered pigs and categorisation of pork meat (Official Gazette 2/85, 12/85 and 24/86).
  - Rulebook on the quality of poultry meat (Official Gazette 1/81 and 15/88).
  - Rulebook on the quality of meat from cattle for slaughter, poultry and wildlife (Official Gazette 34/74 26/75 and 13/78).
  - Rulebook on the quality of meat products (Official Gazette 29/74, 41/80 and 13/78).
  - Rulebook on the quality of poultry meat products (Official Gazette 55/91).
42. Rulebook on the quality of fish, shrimp, shellfish, sea urchins, frogs, tortoises, snails and their products (Official Gazette 65/79 and 48/84).
43. Rulebook on the quality of spices, spice extracts and spice mixtures (Official Gazette 4/85 and 84/87).
44. Rulebooks on the quality of fruit, vegetables and mushrooms:
- Rulebook on the quality of fruit, vegetables and mushrooms (Official Gazette 29/79 and 53/87).
  - Rulebook on the quality of fruit, vegetable and mushroom products and pectin preparations (Official Gazette 1/79, 20/82, 39/89 and 74/90).

- Rulebook on the methods of sampling and carrying out chemical and physical analysis for the control of the quality of fruit and vegetable products (Official Gazette of SFRY 29/83).
  - Rulebook on the quality of edible mushrooms and products from edible mushrooms (Official Gazette 46/91 and 64/91).
45. Rulebooks on the quality of acetic acid and diluted acetic acid:
- Rulebook on the quality of vinegar and diluted acetic acid (Official Gazette 24/89).
  - Rulebook on the methods of sampling and chemical and physical analysis for control of the quality of vinegar and diluted acetic acid (Official Gazette 26/89).
46. Rulebook on the quality of soups, soup stock, sauce concentrate and food additions (Official Gazette 5/82 and 58/85).
47. Rulebooks on the quality of cattle feed:
- Rulebook on the quality of cattle feed (Official Gazette 15/89 and 54/90).
  - Rulebook on the methods of sampling and carrying out physical, chemical and microbiological analysis of cattle feed (Official Gazette 15/87).

**2. Indicate if a table of correspondence between your legislation and EU legislation is already available.**

**Please describe the current status and the foreseen evolution with a precise timetable.**

No tables of correspondence for the applicable legislation in this field, in the Republic of Macedonia have been drafted. The current situation is detailed in questions [01 III C 1](#) and [01 III D 1](#) of this Chapter.

Tables of correspondence shall be prepared in the course of drafting legal acts in this field, in accordance with the scheduled dynamics in the National Programme for Approximation of Legislation with EU Legislation. The above shall also be delivered to the European Commission.

**Rulebook on food contact materials and products**

**Adoption deadline - 2005**

1. Council Directive 89/109/EEC of 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
2. Council Directive 82/711/EEC of 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
3. Directive 93/8/EEC of 1993 amending Directive 82/711/EEC.
4. Directive 85/572/EEC of 1985 laying down the list of stimulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.
5. Directive 90/128/EEC of 1990 relating to plastic materials and articles intended to come into contact with foodstuffs.
6. Directive 92/39/EEC of 1992 amending Directive 90/128/EEC.
7. Directive 93/9/EEC of 1993 amending Directive 90/128/EEC.
8. Directive 93/10/EEC of 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
9. Directive 93/111/EEC of 1993 amending Directive 93/10/EEC.
10. Directive 84/500/EEC of 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
11. Directive 78/142/EEC of 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.
12. Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.
13. Corrigendum to Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.

**RULEBOOK ON LABELLING PRE-PACKAGED FOODSTUFFS**

**Adoption deadline - 2005**

1. Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs.
2. Directive 94/54/EC concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC.
3. Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

4. Regulation (EC) No 1829/2003 on genetically modified food and feed.
5. Directive 94/35/EC on sweeteners for use in foodstuffs.
6. Directive 2002/67/EC on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine.
7. Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs.
8. Directive 87/250/EEC on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer.
9. Directive 90/496/EEC nutrition labelling for foodstuffs.

#### **RULEBOOK ON ADDITIVES IN FOODSTUFFS**

**Adoption deadline - 2005**

1. Directive 94/35/EC on sweeteners for use in foodstuffs.
2. Directive 94/36/EC on colours for use in foodstuffs.
3. Directive No 95/2/EC on food additives other than colours and sweeteners.
4. Directive 88/388/EEC on flavourings for use in foodstuffs.
5. Directive 88/344/EEC on extraction solvents used in the production of foodstuffs.
6. Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs
7. Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.
8. Directive 2004/46/EC amending Directive 95/31/EC as regards E 955 sucralose and E 962 salt of aspartame-acesulfame.
9. Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners.
10. Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs.
11. Directive 82/504/EEC amending Directive 78/663/EEC laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs.

#### **RULEBOOK ON THE MAXIMUM ALLOWED LEVELS OF CONTAMINANTS IN FOODSTUFFS**

**Adoption deadline - 2005**

1. Directive 86/362/EEC on the fixing of maximum levels for pesticide residues in and on cereals
2. Directive 76/895/EEC relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables
3. Directive 90/642/EEC on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables.
4. Directive 86/363/EEC on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin.
5. Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs.
6. Regulation (EC) No 2375/2001 amending Commission Regulation (EC) No 466/2001
7. Regulation (EC) No 472/2002 amending Regulation (EC) No 466/2001.
8. Regulation (EC) No 563/2002 amending Regulation (EC) No 466/2001.
9. Regulation (EC) No 1425/2003 amending Regulation (EC) No 466/2001.
10. Regulation (EC) No 2174/2003 amending Regulation (EC) No 466/2001.
11. Regulation (EC) No 242/2004 amending Regulation (EC) No 466/2001.
12. Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.
13. Directive 96/22/EC concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of  $\beta$ -agonists.

#### **RULEBOOK ON THE MICROBIOLOGICAL SAFETY OF FOODSTUFFS**

**Adoption deadline - 2005**

1. Directive 94/65/EC laying down the requirements for the production and placing on the market of minced meat and meat preparations.
2. Directive 92/46/EEC laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products.
3. Directive 91/492/EEC laying down the health conditions for the production and the placing on the market of live bivalve molluscs.
4. Directive 89/437/EEC on hygiene and health problems affecting the production and the placing on the market of egg products.
5. Directive 80/777/EEC on the exploitation and marketing of natural mineral waters.
6. 93/51/EEC: Commission Decision on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish.
7. 2001/471/EC: Commission Decision on health problems affecting the production and placing on the market of fresh poultry meat.

**RULEBOOK ON THE TYPES OF FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES****Adoption deadline - 2005**

1. **Council Directive 89/398/EEC** of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
2. **Directive 96/84/EC** of The European Parliament and of the Council of 19 December 1996 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
3. **Directive 1999/41/EC** of The European Parliament and of the Council of 7 June 1999 amending Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
4. **Commission Directive 2001/15/EC** of 15 February 2001 on substances that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses
5. **Commission Directive 1999/21/EC** of 25 March 1999 on dietary foodstuffs for special medical purposes
6. **Directive 2002/46/EC** of the European Parliament and of the Council of 10 June 2002 on the approximation of the Laws of the member States relating to food supplements

**RULEBOOK ON THE COMPOSITION AND LABELLING OF DIETARY FOODSTUFFS FOR SPECIAL MEDICAL PURPOSES****Adoption deadline - 2005**

1. **Council Directive 89/398/EEC** of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
2. **Commission Directive 1999/21** of 25 March 1999 on dietary foods for special medical purposes [Official Journal L 91, 07.04.1999]

**RULEBOOK ON THE REQUIREMENTS FOR CEREAL-BASED FOODSTUFFS AND BABY FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN****Adoption deadline - 2005**

1. **Commission Directive 96/5/EC** of 16 February 1996 on processed cereal-based foodstuffs and baby foodstuffs for infants and young children [Official Journal L 49 of 28.02.1996].
2. **Commission Directive 98/36/EC** of 2 June 1998 amending Directive 96/5/EC on processed cereal-based foodstuffs and baby foodstuffs for infants and young children [Official Journal L167, 12/6/1998 P. 0023-0024].
3. **Commission Directive 1999/39/EC** of 6 May 1999 [Official Journal L124 of 18.05.1999].

**RULEBOOK ON THE COMPOSITION AND LABELLING OF MILK-BASED FOODSTUFFS FOR INFANTS – INFANT FORMULA****Adoption deadline - 2005**

1. **Council Directive 89/398/EEC** of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
2. **Commission Directive** of 14 May 1991 on infant formulae and follow-on formulae (**91/321/EEC**)
3. **Commission Directive 96/4/EC** of 16 February 1996 amending Directive 91/321/EEC on infant formulae and follow-on formulae (Text with EEA relevance)
4. **Commission Directive 1999/50/EC** of 25 May 1999 amending Directive 91/321/EEC on infant formulae and follow-on formulae (Text with EEA relevance)
5. **Commission Directive 2003/14/EC** of 10 February 2003 amending Directive 91/321/EEC on infant formulae and follow-on formulae
6. **Commission Directive 2003/5/EC** of 10 January 2003 amending Council Directive 91/414/EEC to include deltamethrin as active substance
7. **Commission Regulation (EC) No 466/2001** of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs [Official Journal L 77 of 16.03.2001]

**RULEBOOK ON THE REQUIREMENTS FOR THE COMPOSITION, FEATURES AND LABELLING OF FOOD SUPPLEMENTS****Adoption deadline - 2005**

1. **DIRECTIVE 2002/46/EC** of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [Official Journal L183 of 12.07.2002].

**RULEBOOK ON THE HYGIENE OF FOODSTUFFS***Adoption deadline - 2005*

1. Regulation (EC) no 853/2004 of the European Parliament
2. And of the council of 29 April 2004 on the hygiene of foodstuffs
3. Regulation (EC) no 853/2004 of the European Parliament
4. And of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs
5. Directive 93/43/EEC of foodstuff hygiene
6. Regulation EC 178/2002 laying down the general principles and requirements of food law, establishing the food safety authority and laying down procedures in matters of food safety
7. Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

**RULEBOOK ON THE RADIOACTIVE CONTAMINATION OF FOODSTUFFS***Adoption deadline - 2005*

EU Measures:

1. Council Directive 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs of feedstuffs following a nuclear accident or any other case of radiological emergency.
2. Council Regulation 2218/89 of 18 July 1989 amending Regulation 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs of feedstuffs following a nuclear accident or any other case of radiological emergency.
3. Council Regulation 737/90 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station
4. Council Regulation 686/95 of 28 March 1995 extending Regulation EEC No. 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station
5. Council Regulation No. 616/200 of 20 March 2000 amending Regulation EEC No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station
6. Council Regulation (EEC) No 737/90 of 01 April 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station

**Preparation of administration and operators:**

**1. Please identify the systems of pre-market approval of foodstuffs which are not in conformity with EU law and indicate whether and when a revision of these is foreseen in order to align them with the EU food law principles (notably regarding operators' prime responsibility for food safety).**

**Please describe the current status and the foreseen evolution with a precise timetable.**

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) regulates the conditions for ensuring the safety of foodstuffs and food contact products and materials, production and circulation, the rights and obligations of natural and legal persons producing or circulating, with the general objective to protect human health, and consumers from misguidance and enabling free circulation on the internal and external market.

Relevant EU directives and regulations that are not incorporated in the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) are going to be incorporated in secondary legislation which is in a stage of preparation. The current status and the foreseen evolution of the National Legislation is answered in questions [01 III B 1](#) and [01 III B 2](#).

Starting form 01.01.2005 the Food Directorate took over the control, notably regarding operators' prime responsibility for food safety, control of foodstuffs and food contact products and materials.

In the legislation of the Republic of Macedonia no system for issuing pre-market approvals in the field of food (from the point of view of the sanitary safety of food) is foreseen.

**2. As guidance for the information which should be provided, take as an example the area of Control/hygiene rules for food as described below:**

- a) Training of the various control officials on inspection and sampling in general and on HACCP (Hazard Analysis and Critical Control Points): state of advancement and future plans;**
- b) HACCP implementation by food operators: state of advancement and future plans;**
- c) laboratories used in hygiene control and foodstuff analysis (chemical, microbiology, GMOs, etc): present or planned activities (with time-table) to comply with EU systems; time-table of accreditation according to EU law with name of accreditation body; methods of sampling and analysis (in general; for contaminants; for food contact materials, etc.);**
- d) procedures for registration and authorisation (if any) or system of listing food establishments: state of advancement and future plans;**
- e) present (and planned) resources (personnel, budget and inspection equipment);**
- f) present (and planned) frequency of controls; planning of inspection activities;**
- g) present (and planned) procedures for encouraging the development of guides of good hygiene practice and for assessing these guides;**
- h) evaluation of the control services (existing or planned audit system);**
- i) management of food complaints, food poisoning cases, enforcement, legal action, appeals;**
- j) control of imported food (existing and planned system).**

**Please describe the current status and the foreseen evolution with a precise timetable.**

**a)**

Within the signed two-year agreement for cooperation of WHO and the Ministry of Health of the Republic of Macedonia, the first WHO seminar on training HACCP instructors (analysis of hazardousness and critical point control) was successfully held in the Republic Healthcare Bureau from 11<sup>th</sup> to 15<sup>th</sup> November 2002 in Skopje, attended by 14 inspectors (8 sanitary inspectors, 2 veterinary and agricultural inspectors, respectively), who completed the provided trainer training as a contribution to enhancing the capacities of the Ministries dealing with foodstuff safety.

The Minister of Health by adopting special regulations based on the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) and Food Contact Products and Materials shall prescribe and stipulate all requirements for individual entities working with foodstuffs and they are going to be obliged to implement the HACCP system. The preparation and adoption of the Rulebook on general foodstuff safety requirements (foodstuff hygiene section) is foreseen to be harmonised with the EU Directive 93/43 by the end of 2005.

**b)**

In accordance with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02), foodstuff producers and traders are obliged to apply in the production and circulation of foodstuffs system for risk assessment of critical control points (HACCP) covering:

1. Analysis of potential foodstuff contamination risks,
2. Identification of stages in the technological process where opportunities exist for the occurrence of potential risks and adoption of a decision as to which of the stages can be expected to be a critical point,
3. Establishment and application of procedures for monitoring and controlling established critical point hazards, and
4. Periodical inspections of the activities under items 1-3 as regards their effectiveness or renewal in the event of changes in the foodstuff production and circulation process, as well as keeping written records of the periodical inspections.

With the start of work of the Food Directorate (01.01.2005), it is planned to develop an implementation plan for the entire food industry, distribution and circulation with timeframes in accordance with the requirements met by the facilities, and the degree of risk. Food inspectors will be trained to provide adequate advice and develop special implementation timeframes for each facility respectively, in accordance with the general timeframe.

Currently, there is a small number of production facilities implementing the HACCP system, but a large number are at the implementation stage.

The GTZ project for establishing a HACCP info centre with a website (<http://www.haccpinfo.org.mk>) was successfully accomplished in 2003.

Since 2002 GTZ have been working on a project for implementation of the HACCP system in ten production facilities in the Republic of Macedonia with external verification.

Several workshops have been held within the Ministry of Economy on the requirements for implementing the HACCP system, as well as for the system itself. Several international projects (GTZ, USAID, SIDA, SEED, the FAO office in the Republic of Macedonia etc.) are engaged in the education of primary producers and processors for the implementation of the systems for good agricultural practices, good production practices and the HACCP system, as well as in controller education.

**c)**

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) provides for examination and analyses of foodstuff and food contact items to be carried out by accredited laboratories, where laboratory accreditation is carried out in accordance with the regulations on accreditation. The responsible institution for the implementation of laboratory accreditation is the Accreditation Institute of the Republic of Macedonia.

There is currently no accredited laboratory in the Republic of Macedonia. Pending accreditation of one, the examination and analysis of foodstuff and food contact products and materials shall be carried out by the existing laboratories authorised by the Minister of Health and the Minister of Agriculture, Forestry and Water Economy.

Laboratories authorised by the Ministry of Health to carry out analysis and super analysis of foodstuffs and consumer goods of import and domestic production are the Republic Healthcare Bureau, Skopje, and the Faculty of Veterinary Medicine, Skopje, examining sanitary safety with all parameters. The other ten laboratories of regional healthcare institutes carry out analysis of foodstuff of domestic production and in domestic circulation. The food laboratories in the Republic Healthcare Bureau and the Faculty of Veterinary Medicine have the most sophisticated examination equipment and they employ highly expert staff with a doctrinal approach to laboratory examinations for quick and accurate analysis with established methodology.

The food laboratories (microbiological, toxicological and radiological) of the Republic Healthcare Bureau are at the stage of applying for accreditation.

The remaining ten food laboratories of healthcare institutes (microbiological and for examination of physical and chemical parameters) shall also start the accreditation process.

State monitoring is defined with the Programme for Preventive Healthcare, adopted by the Government of the Republic of Macedonia upon the proposal of the Minister of health each year and it is published in the Official Gazette of RM (sanitary and hygiene section) where the programmes to be carried out by the ten regional institutes and the Republic Healthcare Bureau as regards monitoring food contaminants, drinking water in rural areas, radiological contamination of foodstuffs and control of consumer goods, are defined. These programmes are funded from the budget of the Republic of Macedonia.

For example, the food laboratories within the Republic Healthcare Bureau have the most sophisticated examination equipment and work with highly expert staff who regularly attend seminars in EU countries.

They carry out:

- laboratory establishment of the hygiene quality of the food product;



- laboratory establishment of contaminants in foodstuffs by detection of pesticides, heavy metals, mycotoxins, and additives;
- laboratory identification of the presence of organic and inorganic chemical contaminants in a food product;
- laboratory establishment of contaminants in drinking water, mineral water, in accordance with the criteria and regulations in force in the Republic;
- establishing contaminants in soil samples;
- expert participation in the development of regulations and standards on referent healthcare and environmental laboratory procedures, norms and working conditions;
- training and education of analytics staff in the field of sanitary chemistry and toxicology.

As regards the methods of analysis of foodstuff and food contact items, they are not specifically regulated in Macedonian legislation. Where possible, internationally acknowledged and referent methods are used, as well as alternative methods described in collections (AOAC, CAC, Food chemical codex etc.). In certain cases, unofficial empirical methods are used.

### **Heavy metals (in all foodstuffs)**

Quantitative establishment of arsenic and selenium by applying graphite atomic absorption spectrometry;

Quantitative establishment of metals by flame atomic absorption spectrometry with previous dissolution of the sample in a HCl / HNO<sub>3</sub> concentrate;

Quantitative establishment of heavy metals with the method of atomic absorption spectrometry following microwave mineralization.

### **Analysis of pesticide residues**

#### **Fruit, vegetables, juice and tomatoes**

Gas chromatographic establishment of pesticides containing chlorine and phosphorus following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns;

Gas chromatographic establishment of pesticides containing phosphorus and sulphur following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns;

Gas chromatographic establishment of pesticides containing phosphorus, sulphur and nitrogen following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns;

Gas chromatographic establishment of pesticides containing chlorine, nitrogen, phosphorus and sulphur following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

Gas chromatographic establishment of pyrethrines following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

#### **Wheat and wheat products, spices, pulverised fruit, tea**

Gas chromatographic establishment of pesticides containing chlorine and phosphorus following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

Gas chromatographic establishment of pesticides containing phosphorus and sulphur following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

Gas chromatographic establishment of pesticides containing phosphorus, sulphur and nitrogen following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

Gas chromatographic establishment of pesticides containing chlorine, nitrogen, phosphorus and sulphur following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

Gas chromatographic establishment of pyrethrines following clean-up by gel permeation chromatography and chromatography with mini-silica gel columns

### **Fat and edible fat, essence oils**

Gas chromatographic establishment of organ chlorine pesticides with previous dissolution of fats in petrol ether (40-80) or in *n*-hexane and participation of acetone/petrol ether 40-80 (*n*-hexane)

### **Meat, cheese, fish**

Gas chromatographic establishment of organ chlorine pesticides with previous dissolution of fats in petrol ether (40-80) or in *n*-hexane and participation of acetone/petrol ether 40-80 (*n*-hexane)

Fat extraction by petrol ether 40-80 (*n*-hexane) with a Soxhlet apparatus

Fats and edible fats, wheat and rye flakes, oats, walnuts, hazelnuts, peanuts, and oilseeds

Gas chromatographic establishment of organ chlorine pesticides with previous dissolution of fats in petrol ether (40-80) or in *n*-hexane and participation of acetone/petrol ether 40-80 (*n*-hexane)

Fat extraction by petrol ether 40-80 (*n*-hexane) with a Soxhlet apparatus

### **Analysis of mycotoxins**

### **Walnuts, hazelnuts, peanuts, pistachios, almonds, cereals, tea, spices**

Establishing aflatoxins:

- B1
- B2
- G1
- G2

by thin-layer chromatography (TLC).

**Sample extraction is carried out by chloroform and extract purification is done with a florisil column**

Establishing aflatoxins:

- B1
- B2
- G1
- G2

with high-pressure liquid chromatography (HPLC), with a fluorescent detector (FL). Sample extraction is carried out by chloroform and extract purification is done with a florisil column

### **Proteins (in all foodstuffs)**

Establishing protein content with the Kjeldahl method with Kjeltec Auto 1030 Analyzer – micro procedure

## Milk, dairy products

Establishing milk volume mass by lactodensimeter  
Establishing acidity according to Soxhlet-Henkel with a titration, colorimetric method with 0.1 M NaOH modification according to Morres  
Establishing fat with the Gerber acido-butyrometric method  
Establishing dry matter with the gravimetric method of analytic scales  
Proving milk pasteurisation with the Andersen and Petersen method with phosphate test  
Proving crude impurity in milk with the filter method  
Establishing the freezing point of milk with the Beckman thermometer  
Establishing milk serum refraction reading on a refractometer  
Establishing lactose and sucrose by reduction of the Fehling solution with tritration  
Establishing water in milk with the gravimetric method of analytic scales  
Testing solubility by reconstructing powder milk and separating dry matter  
Establishing fat with a cream butyrometer according to the Gerber method  
Establishing cheese fat with a cheese butyrometer according to the Gerber method  
Establishing water according to the drying method  
Establishing NaCl with the Volhard titration method  
Establishing water in butter according to the drying method  
Establishing water in butter according to the evaporation method  
Establishing fat with a butter butyrometer according to the Gerber method  
Establishing free carbon acid (CO<sub>2</sub>) with the titration method with 0.1 M NaOH  
Establishing alcohol with the gravimetric method with a pycnometer

Sanitary safety is established for:

- vessels and kitchen utensils
- Foodstuffs packaging
- toys
- tobacco products

(Establishing sanitary safety of consumer goods according to legal and expert regulations as regards heavy metals (Pb, Cd, Co, Cr, As, Hg, Se, Ni), and organic and inorganic compounds (polycyclic aromatic carbohydrates, naphthylamin, benzidine, acrylo-nitril, vinyl chloride, phenols, cresols, identification of all plastic material);

## EQUIPMENT

- gas chromatograph with a fat spectrometer PERKIN ELMER, DETECTOR Jon Trap 800;
- gas chromatograph with the necessary detectors (FID, ECD,NPP) VARIAN M-3700;
- gas chromatograph HEWLET PACKARD with HEAD SPACE HS - 40;
- liquid chromatograph PERKIN ELMER 235 C - detector - HPLC;
- AAC - furnace and cooling system PERKIN ELMER M 3110/MHS 10;
- AAC – furnace, cooling system and graphite cuvette - PERKIN ELMER - AA 4100/HGA 700;
- thin-layer chromatography system – GAMAG;
- infrared spectrometer IR-PERKIN ELMER - PARAGON 1000;
- spectrophotometer UV-VIS PE - LAMBDA-12 with a continuous-flow cuvette;
- other accessory equipment.
- Establishing sanitary safety of consumer goods according to legal and expert regulations as regards heavy metals (Pb, Cd, Co, Cr, As, Hg, Se, Ni), and organic and inorganic compounds (polycyclic aromatic carbohydrates, naphthylamin, benzidine, acrylo-nitril, vinyl chloride, phenols, cresols, identification of all plastic material;
- training and education of analytics staff in the field of sanitary chemistry and toxicology.

Sanitary safety is established for:

- vessels and kitchen utensils
- Foodstuffs packaging

- toys
- tobacco products
- 

### **EQUIPMENT**

The unit applies contemporary diagnostics methods in its work and is equipped with the necessary apparatus and laboratory material for research in this field, as follows:

- AAC – with a furnace method PERKIN ELMER M 372;
- AAC – furnace, cooling system and graphite cuvette - PERKIN ELMER M 3110/MHS 10;
- other laboratory equipment supplies.

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) mentions that foodstuffs containing or consisting of genetically modified organisms, produced from genetically modified organisms shall be referred to as foodstuffs produced by innovative technology which is still not accessible for public use. Article 6 clearly defines that vegetable foodstuffs and vegetable food products in whose seed material there has been genetic intervention shall be considered unsafe foodstuffs and the production and circulation of unsafe foodstuffs is prohibited.

There are currently no mechanisms in the Republic of Macedonia for the control of GMO in foodstuffs. There is no GMO monitoring facility in the Republic of Macedonia. In the event of suspicion of such foodstuffs, the Ministry of Health forwards examination samples to accredited laboratories in EU countries.

In the 2005 framework plan, it is provided to purchase a Real time PCR for Republic Healthcare Bureau and by completing the existing laboratory apparatus to commence the process of establishing a GMO laboratory in the Republic of Macedonia.

The Ministry of Agriculture, Forestry and Water Economy is responsible for the import, control and use of products of vegetable origin containing GMO and intended for human and animal consumption. The Ministry of Environment and Physical Planning shall be responsible in future for assessing the risk and the influence of GMO on the environment. In future, the Ministry of Health shall manage the assessment of the risk and the influence of GMO on the human population. These three ministries need to be well-prepared to develop mutual cooperation on the practical implementation of legislation in future, thus regulating biotechnology and bio-safety.

The provisions of the Carthage Protocol on bio-safety (when it is ratified) together with the provisions of the appropriate EU directives will be adequately integrated in the new law relating to genetically modified organisms. The new law will regulate issues relating to the import, marketing, use in production of genetically modified organisms, deliberate release in the environment and risk management. This law is to cover, in addition to genetically modified micro organisms, genetic transformation in plants, animals and humans. This is the only way in which the new law will present an instrument for ensuring the safe development of contemporary biotechnology in Macedonia.

In the Republic of Macedonia the project National Framework for Biological Safety of UNEP-GEF is currently underway and it is part of the global UNEP-GEF project, whose objective is to help the countries (currently 119 are involved) in the implementation of the Carthage Protocol on bio-safety through the development and implementation of the National Framework for Bio-safety.

### **d)**

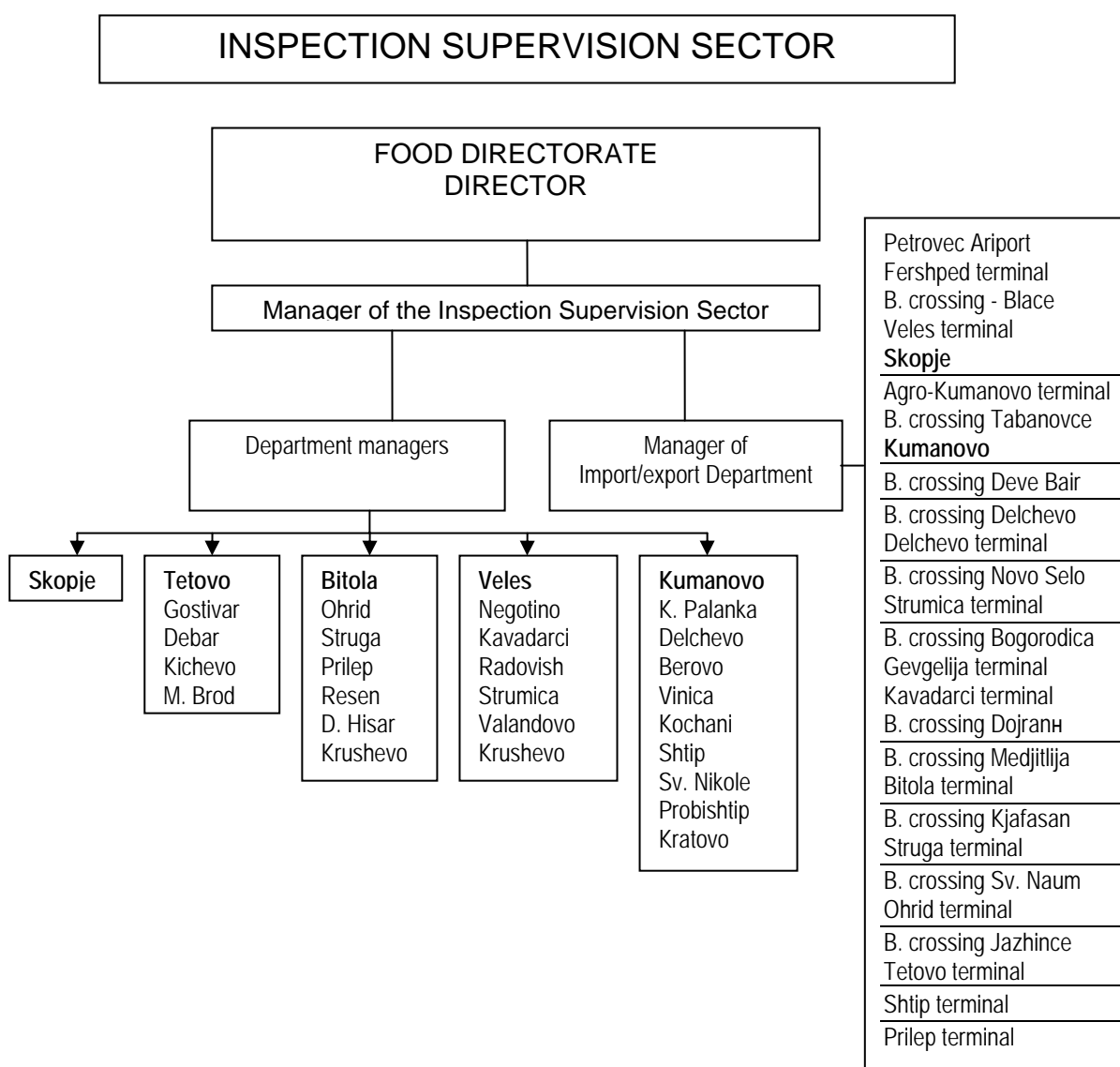
The Minister of Health, in accordance with the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02), will adopt a special regulation regulating the conditions for carrying out operations for the facilities for the production and circulation of food, which will be in accordance with EU standards. This regulation is at the preparation stage and its adoption is expected in 2005/2006.

e)

The total number of food inspectors in the Food Directorate, Inspection supervision sector is 58, organised on a regional level. The inspection is funded from the Budget of the Republic of Macedonia, while part of the funds are provided from providing services at the request of the client.

The provision of funds for the equipment of the inspection service will take place gradually, in accordance with the funds allocated by the 2005 Budget Programme. The funds projected do not meet entirely the needs for carrying out inspection supervision pursuant to legal regulation and this shall require procuring additional funds.

Organisation chart for inspection supervision within the Food Directorate 29/e:



f)

With the annual plan the Food Directorate controls foodstuff producing organisations by clear guidelines to regional inspectors. The programme provides and develops the method and choice of taking samples, as well as the analysis parameters that need to be prepared, for each of the finished foodstuffs series. Laboratory analysis shall be carried out for all product safety parameters. On the basis of the Inspectorate programme, the regional units develop detailed plans that, in addition to taking samples for laboratory examination, cover the activities related to the control and inspection of

the facilities for food production and circulation, their hygiene conditions, the hygiene of the employees in production and of the people in direct contact with food. One of the projected activities is carrying out food monitoring for the purpose of establishing various nutrients, contaminants, additives and other ingredients and matter in order to establish the intake of individual matter in the organism and to assess the risk to humans from consuming unsafe food.

The Republic Healthcare Bureau, Skopje, and the ten healthcare institutes implement the minimal annual plans for taking drinking water samples. The number and the samples taken are regulated with the Rulebook on the safety of drinking water ("Official Gazette of RM" No. 57/04), which corresponds to European legislation.

**g)**

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) is in the function of creating normative and legal acts and with the establishment of the Food Directorate it is planned to develop a guide on good production practice, a guide on good laboratory practice, as well as a guide for the application of the HACCP system. The guides will be developed in cooperation with all the entities working in the field of food safety.

**h)**

There is a planned system of inspection service review. Each inspector shall be up for review twice a year on randomly chosen cases where decisions for prohibition have been issued, cases for which the inspector filed a request for initiation of misdemeanour procedure to the court or upon complaints (most often lodged by the Consumer Association). The first control is from the department manager, then from the sector manager on the basis of the volume of activities carried out, delivered monthly, periodical or annual reports, and by way of inspection of decisions. Administration control is carried out entirely on the field by the Ministry of Health through the Inspectorate. In accordance with the Law on Civil servants, there shall be evaluation of completed work of the inspectors.

This type of control has proven successful as regards the carried out situation analysis for a period of three years and it is considered that the Food Directorate will carry out control with the same plan, but, in that, will take into account all European experiences with a positive result.

**i)**

According to the existing condition, the inspector of the State Sanitary and Health Inspectorate is authorised to prohibit the import of unsafe foodstuffs and to determine a procedure for such foodstuffs. The inspector can order return to the export country, its destruction if such a procedure does not pollute the environment or, at the proposal of an expert organisation, to put it to a different purpose following additional analyses.

The decision of the food inspector is final in the administrative procedure and can be challenged with an appeal to the Ministry of Health or to the competent court.

In cases where there are indications that there is unsafe foodstuffs on the market, regardless the fact whether it is of domestic or other origin, the Food Directorate from 01.01.2005 issues following the inspection a decision for withdrawal of the food from circulation.

In the event of food poisoning, the food inspector, in cooperation with an epidemiologist from the regional healthcare institute, shall go out on the field to the facility for which there is suspicion that it is the source of a disease outbreak, they shall establish the hygiene condition of the facility, take samples of the food found in the facility for analysis and shall order measures provided in the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) (temporary prohibition of the work of the facility, removing from the work place persons suspected to be carriers, measures for DDD and other measures). Following the completion of all analyses, depending on the obtained results, they shall initiate a procedure (penal measures) against the legal and responsible person. The penal measures can be fines, closure of the facility from three months to a year and if detriment of health of the persons who have consumed unsafe food is proven, criminal charges shall be filed as well.

j)

The food imported into the Republic of Macedonia for the purpose of putting into circulation must satisfy the provisions of the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02). The supervision of sanitary safety of foodstuffs imported into the Republic of Macedonia is the responsibility of the import-export inspection supervision department, and it is carried out by food inspectors at customs terminals and public customs warehouses on the territory of the Republic of Macedonia.

The inspection of the safety of imported food on the part of the Food Directorate, import-export inspection supervision department, is carried out at customs terminals. The customs service cannot clear customs before the foodstuff inspectors establish foodstuff safety and approve its import with a decision. It is required that the shipment always carries a sanitary certificate from an authorised institution of the exporting country.

The coordination of the work of inspectors for imported-exported foodstuffs is carried out centrally by the manager of the department with offices in the Food Directorate; all inspectors shall be provided with guidelines for the actions of each issue in the field of activities, and the relevant notifications shall be delivered. The manager directly organises and focuses the work of the foodstuff inspectors on the field. Feedback is delivered with the regular monthly reports on the activities and manager controls carried out. The establishment of IT support will enable daily data input in the central database at the Food Directorate.

Furthermore, the Food Directorate is incorporated in the National Strategy on Integrated Border Management and the National Operative Plan for Integrated Border Management in the Republic of Macedonia, funded by the EU and managed by the European Agency for Reconstruction.

**3. Please apply similar questions in the case of other structures and procedures (existing or to be set up) relating to:**

- a) the application for novel food, including GMOs;**
  - b) the food assessment body for novel food, including GMOs;**
  - c) the Rapid Alert System for Food and Feed (RASFF);**
  - d) approval of irradiation facilities, if any;**
  - e) any other procedure for authorisation/accreditation as provided for in the EU legislation.**
- Please describe the current status and the foreseen evolution with a precise timetable.**

a)

There are currently no mechanisms in the Republic of Macedonia for GMO control in foodstuffs. In the event of suspicion of such foodstuffs, the Ministry of Health forwards examination samples to accredited laboratories in EU countries.

Foodstuffs containing GMO, according to the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" No. 54/2002), fall under "food produced by innovative technology":

- food produced by new procedures causing substantial changes to the use of the food;
- consisting of or containing GMO;
- containing ingredients with newly or deliberately modified primary molecular structures;
- consisting of or isolated from plants grown in a non-traditional fashion and for which there is no experience of safe use.

The applying procedure for "novel" foodstuffs shall be regulated by adopting special provisions based on the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" No. 54/02), which shall be within the competence of the Food Directorate.

**b) Does not exist.**

**c)**

In cooperation with the Ministry of Agriculture, Forestry and Water Economy, the Veterinary Directorate and other relevant institutions, monitoring of the sanitary safety of foodstuffs and animal feed will be carried out, scientific studies will be developed on establishing a unified methodology for risk assessment at all stages of production, on foodstuffs and animal feed processing and distribution, as well as on promoting the process of risk assessment regionally.

**d)**

The general conditions for start of work for facilities using radioactive sources are laid down in the Law on Protection from Ionizing Radiation and Radiation Safety ("Official Gazette of RM" No. 48/2002).

No special regulations for approving/licensing irradiation facilities in the Republic of Macedonia have been adopted.

In the Republic of Macedonia there are no irradiation facilities or a detailed act regulating this issue.

The Republic of Macedonia does not have standards for food processed by way of irradiation.

For future evolution see answer to the question [22 II J 3](#)

**e)** Does not exist.



## IV. NON-HARMONISED AREAS

### *A. Measures having an equivalent effect to quantitative restrictions*

**1. Do measures exist in the laws, regulations or administrative provisions adopted at national or local level on the production, distribution and marketing of food products and industrial products:**

**a) Relating to the price of such products (e. g. fixing the prices above or below which the importation or marketing of a product is prohibited or restricted, laying down profit margins or other price components, etc.)?**

There are no legal measures, regulations or provisions in the Republic of Macedonia relating to product prices.

**b) Which require automatic or non-automatic import licence or permits for imported goods (e.g. licence for import of automobiles)?**

There are no legal measures, regulations or provisions in the Republic of Macedonia requiring an import license or permits for imported goods.

**c) Which make access to the domestic market conditional upon having an agent or representative in the territory of your country (e.g. legislation which provides for the sale of certain goods in your country subject to authorisation that may be obtained only by a person established there)?**

There are no legal measures, regulations or provisions in the Republic of Macedonia enabling access to the domestic market provided that there is one agent or representative on the territory of Macedonia.

**d) Which oblige importers to have storage facilities in the territory of your country (e.g. legislation applying only to imported goods which require these imported goods to be stored for some time before being marketed)?**

Companies importing oil derivatives are obliged to have special warehouses. This obligation applies for wholesale importers and traders as well.

**e) Which impose on the marketing of imported products conditions (relating in particular to shape, size, weight, composition, presentation, identification and packaging, labeling) that are different from those imposed on domestic products or which require or encourage the use of certain type of packaging (shape, size, composition) for the marketing of a certain product, whether domestic or imported (e.g. requirement that some goods may only be sold in a package with special form)?**

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" No. 54/2002) provides certain requirements for packaging, types and size of packaging, net weight or volume of the product, composition, identification and labelling, but these conditions refer to all products, regardless whether they are of domestic produce or imported. For all stipulated requirements, the producer, foodstuff trader or importer are obliged to satisfy the conditions under the Macedonian Food Code. Part of the rulebooks has been developed and part is at the development procedure and they comply with European legislation.

**f) Which oblige economic operators to label their product with the "Made in ..." marking (obligatory origin marking)?**

Does not exist.

**g) Which encourage or authorise the purchase (by individuals or public authorities) of domestic products alone or give preference to the purchase of such products in advertising campaigns (e.g. promotion actions with the participation of public authorities applying only to goods produced by producers in your country or from domestic raw materials)?**

Does not exist.

**h) Which exclude imported products alone, in full or in part, from the possibility of using domestic facilities or equipment or which reserve the use of such facilities or equipment, in full or in part, for domestic products alone?**

Does not exist.

**i) Which subject imported products to controls, other than those inherent in customs clearance procedures, which are not carried out on domestic products (e.g. veterinary, sanitary, phytosanitary and other controls)?**

Inspection authorities enforce exactly the same measures for control of both domestic and imported goods.

**j) Which allow only traders holding a production licence or wholesale licence to import some goods (e.g. licensing system for the production and wholesale of some goods, which allow only the licence holder to import these goods)?**

There are no measures in the Republic of Macedonia enabling only traders with a production or wholesale import license to import certain goods.

**k) Which creates monopolies of sale of some goods (e.g. tobacco products, alcohol products, etc)?**

There are no measures in the Republic of Macedonia creating a monopoly of the sale of certain goods.

**l) Which reserve certain trade names for domestic products alone and, if so, on what conditions (e.g. rules which reserve the use of a certain description to products prepared in your country from domestic raw materials)?**

There are no measures in the Republic of Macedonia enabling the use of registered names solely for domestic products.

**2. Do you have any information – albeit incomplete – which would make it possible to assess the number of times your authorities intervened to prohibit the marketing of products or withdraw products from the market during 2002 and 2003 for any reason whatsoever, e.g. health risk, incomplete labelling, inadequate consumer information, failure to comply with compulsory standards, etc.?**

**Please describe the current status and the foreseen evolution with a precise timetable.**

The State Market Inspectorate, as an authority within the Ministry of Economy, carries out control of foodstuffs and agricultural products in accordance with the Law on Quality Control of Agricultural Products and Foodstuffs in the Foreign Trade ("Official Gazette of RM" 5/98).

Data on the control of imported foodstuffs and agricultural products carried out:

Description	2002	2003	2004	TOTAL
Number of submitted applications for quality control	18.122	17.592	13.168	48.882
Controlled quantities in tons	1.029.838	627.631	402.359	2.059.828
Number of applications for which samples for analyses have been taken	12.606	11.681	9.119	33.406
Controlled quantity of which samples have been taken (in tons)	862.003	463.646	296.812	1.622.451
Issued certificates of quality	14.439	13.904	10.440	38.783
Quantity of products for which certificates of quality have been issued (in tons)	560.751	725.000	336.326	1.622.077
Issued certificates with organoleptic examination	6.326	5.947	4.166	16.439
Quantity for which certificates with organoleptic examination have been issued (in tons)	164.152	398.600	112.984	675.736

Issued certificates with sampling	7.849	8.430	5.793	22.072
Quantity of issued certificates with sampling (in tons)	396.585	533.549	225.691	1.155.825
Returned and destroyed products due to inappropriate quality	497 tons	67 tons	258 tons	822 tons

Inappropriate quality were the grounds for 73 decisions for denied applications for importing foodstuffs and other products, due to incompliance with the prescribed parameters in legal and secondary legislation acts on: refreshment drinks, instant drinks, energy drinks, preserved fruit and vegetables, edible fat, cooking salt, dried fruit, sugar, rice, beans, flour, confectionery, dates, grape distillate for alcoholic beverages, chewing gum, additives, shorts, cream etc.

Data on the control of foodstuffs and agricultural products of domestic produce carried out:

Description	2003
Total inspections:	25.917
Decisions in administrative procedure	4.101
Claims for initiating a misdemeanour charge	9.266
Confiscated products	13.333.675
Products with an expired period of use withdrawn from circulation	1.263.901
Products withdrawn from circulation on other grounds	4.108.861
On-the-spot penalties	415
On-the-spot fines	909.000
Citizen complaints and reports	942
Police reports	471

The table indicates that in 2003 there have been 25,917 inspections carried out, most of which, i.e. 17,228 inspections, in trade, and the others in tourism and catering, artisanship, as well as for the quality of foodstuffs.

Decisions in an administrative procedure mainly refer to satisfied minimum technical and other requirements prescribed by law, not keeping or not updated records of procurement and sales etc. The total of 9,226 claims to basic courts for initiating a misdemeanour charge relate to infringements of legal regulations in trade, catering, artisanship, as well as consumer protection in several areas. In that period inspections also focused on fighting piracy, hence the greatest numbers of confiscated goods were pirate CDs, DVDs etc., who were destroyed at the Drisla landfill following the end of the court or other procedures.

The Veterinary Directorate, in accordance with the Law on Veterinary Healthcare ("Official Gazette of RM" No 28/98) has carried out in the course of 2003 a total of 13,360 *ex officio* inspections of shipments of animal origin, 7,964 of which in import, 1,023 in export and 4,373 in transit.

At the controls and inspections of the process of production and circulation, the following has been confiscated as hygienically unsafe products: meat – 54,091 kg in internal circulation, 2,513 kg imported, and 25,541 exported; meat products - 24,814 kg in internal circulation; dairy products – 17,655 kg in internal circulation; fish and fish products – 2,785 kg in internal circulation.

The State Agricultural Inspectorate, as an authority within the Ministry of Agriculture, Forestry and Water Economy - in addition to its general authorisations under the special regulations referred to in the Law on Agricultural Inspection, as a primary law stipulating provisions on adopting a decision for prohibition, withdrawal from circulation and removing flaw, temporary seizure with a receipt for temporarily seized items – shall also carry out inspection supervision on the grounds of other laws in the field of agriculture and fishing, as follows:

- The Law on Plant Protection ("Official Gazette of RM" No. 25/98 and 6/2000)
- Law on Quality and Quality Control of Fertilizers (Official Gazette of SRM 10/73 and Official Gazette of RM 83/92)
- The Law on Fisheries ("Official Gazette of RM" No. 62/93)
- Law on seed and plant materials and multiplication materials, type adoption, certification and protection ("Official Gazette of RM" No. 41/2000)
- The Law on Tobacco ("Official Gazette of RM" No. 69/96 and 15/98)

- The Law on Breeding Livestock (“Official Gazette of RM” No. 61/97)

The inspection supervision of the State Agricultural Inspectorate under this legal regulation is towards consistent enforcement of the provisions from these laws in order to protect consumers, end beneficiaries, human health and the environment in general.

The work of the State Agricultural Inspectorate in the past two years related to the aforementioned laws has been the following:

In 2002 state agricultural inspectors have carried out a total of 3,049 controls, written 2,643 minutes, adopted 291 decisions for removal of established flaws, and submitted 437 claims for initiating a misdemeanour charge, 35 of which criminal procedures related to the Law on Fisheries.

The subjects of supervision in the controls were:

- 10.919 tons of various seeds, where 42,277 kg of various seeds have been removed from circulation and temporarily seized with a decision as they have not complied with the declared quality, the expiry date had exceeded, the declaration had not been in Macedonian, the packaging had not been original, no origin stated, i.e. illegally imported.
- 708.063 items of various types of saplings (fruit and viticulture), where 15,760 items of various types of saplings have been temporarily seized, and a large portion of them destroyed, as they were without origin, declaration and sanitary safety.
- 14.858 tons of fertilisers, 2,836 tons cattle feed, and 54 tons of cattle feed have been removed from circulation and use due to established flaws and as they did not fit the declared quality.
- 82.534 kg/l of various plant protection chemicals, where 2,935 kg/l of various plant protection chemicals have been temporarily seized due to expired date of declaration, no origin, no original packaging, declaration and instructions for use not identical with circulation approval, as well as due to circulating chemicals prohibited for use on the territory of the Republic of Macedonia.
- due to violation of the legal regulation 247 kg of cut tobacco intended for sale on green markets, whose sale is prohibited, have been temporarily seized, or the total amount of temporarily seized unprocessed tobacco leaves is 1,915 kg because it has moved between regions.
- 3.199 items of various fishing tools and 1,873 kg of fish have been temporarily seized due to fishing with not allowed means, at night, during spawning periods, i.e. during closed season, as well as due to pollution of fishing waters with detrimental and hazardous matter jeopardizing the fish fund.

During controls for the precise establishment of the quality of removed seeds, fertilizer, cattle feed and fish, agricultural inspectors have taken a total of 33 samples forwarded to laboratory examination. Results show that 20 are in order, 10 samples have flaws and the results for 3 delivered samples have still not arrived.

In 2003 state agricultural inspectors have carried out, in accordance with the abovementioned laws, a total of 4,007 controls, written 3,698 minutes, and adopted 535 decisions for removal of established flaws and stopping operation, and submitted 764 claims for initiating a misdemeanour charge and 18 claims for criminal procedure in accordance with the Law on Fisheries, for operating during closed season; or a total of 782 procedure claims have been filed.

The subjects of supervision in the controls were:

- 8.037 tons of various seeds, where 77.480 kg of various seeds have been removed from circulation and temporarily seized with a decision as they have not complied with the declared quality, the declaration had not been in Macedonian, the expiry date on the declaration had exceeded, no origin stated, illegally imported.
- 1.365.467 items of various types of saplings (fruit and viticulture), where 67,707 items of various types of saplings have been temporarily seized, and a large portion of them destroyed, as they did not fit the prescribed quality, did not have the appropriate documentation, were without origin and did not have the appropriate health certificate.

- 8.146 tons of fertilisers, where 1,039 tons have been removed from circulation and use with a decision, due to inappropriate declaration and unoriginal packaging.
- 2.509 tons of cattle feed, inspectors have, with a decision, removed from circulation and use 112 tons for removing flaws, as they did not fit the declared quality.
- during control, due to violation of legal regulations 6 kg of cut tobacco and 1,700 kg of unprocessed tobacco in leaves have been temporarily seized, or a total of 1,706 kg of tobacco have been temporarily seized.
- 1,651 items of various fishing equipment and 1,363 kg of fish have been temporarily seized due to violation of legal provisions, hunting during closed season with illegal means.

During controls for precise establishment of the quality of removed seeds, fertilizer and cattle feed a total of 14 samples have been taken and forwarded to laboratory examination, and the results state that 7 of them are in order, 6 were not, while results are pending for one more sample.

In the course of 2003 the State Sanitary and Health Inspectorate, on the basis of the annual report on field activities and received laboratory analyses, issued information for all products not safe for humans and enforced the penal provisions of the legal regulation within the competence of the service.

The implementation of activities within the national monitoring of sanitary safety of foodstuffs in the Republic of Macedonia is carried out by authorised professional institutions: The Republic Healthcare Bureau, the ten regional healthcare institutes, the Faculty of Veterinary Medicine, as well as the competent inspection services: The State Sanitary and Health Inspectorate, the State Market Inspectorate and Veterinary Inspection. Operations are carried out for import, production and circulation.

In the following annexed tables: 1 to 19 give an overview of all laboratory tested products. In all the cases where positive results have been received, i.e. that the products are not safe for use with a decision of the State Sanitary and Health Inspectorate, they are returned to the country of export or are destroyed under inspection supervision by an authorized professional institution.

The procedure for products originating from the Republic of Macedonia is similar, i.e. the product is destroyed or re-appropriated with a previous expert opinion from an authorised institution.

In the course of 2003, twelve claims for initiating a misdemeanour charge have been filed to the competent court due to unsafe imported products and not acting upon the decision issued by the state sanitary and health inspectors. A total of 128 claims for initiating a misdemeanour procedure have been filed for products of domestic produce due to failure to act upon a decision from an inspector, as well as 12 reports for initiating a criminal procedure due to detriment to human health due to unsafe food.

In the event of detriment to human health, criminal charges are files, as well as a ban on operations from three months up to one year.

Figure 1. Chemically tested foodstuffs

	Total examined	number	Unsafe	
			Number	%
Total RM		37,283	1,163	3.1
Imported		30,204	496	1.6
Domestic produce and circulation		7,079	667	9.4
Industrial produce		2,876	137	4.7
Artisan produce		2,684	309	11.5
Circulation		1,519	221	14.5
Source and processing: Internal report of the State Sanitary and Health Inspectorate				

Figure 2. Extent of chemically analysed samples and foodstuffs

Authorised institution	Total		Circulation domestic produce		Import	
	Total	Unsafe %	Total	Unsafe %	Total	Unsafe %
Republic Healthcare Bureau	15,282	2.0	750	4.8	14,532	1.9
Veterinary institute	13,753	1.4	1,093	2.7	12,660	1.3

Regional Healthcare Bureaus	8,248	6.5	5,236	11.5	3,012	1.3
Total	37,283	3.1	7,079	9.4	30,204	1.6
Source and processing: Internal report of the State Sanitary and Health Inspectorate						

Figure 3. Extent of examined group parameters

Parameter	Total	Import		Circulation and domestic produce	
		Total	Unsafe	Total	Unsafe
Quality	28,452	22,331	274 (1.23%)	6,121	456 (7.45%)
Additives	5,098	3,757	101 (2.6%)	1,341	9 (0.7%)
Pesticides	10,573	9,854	4 (0.04%)	719	0
Heavy metals	15,407	14,530	5 (0.03%)	877	6 (0.68%)
Mycotoxins	2,981	2,768	46 (1.66%)	213	0
Microbiological safety	26,695	15,451	29 (0.19%)	11,244	760 (6.76%)
Antibiotics	5,031	4,517	0	514	0

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 4. Extent of examined contaminants per authorised institutions

Authorised institution	Pesticides	Heavy metals	Mycotoxins	Antibiotics
Republic Healthcare Bureau	3,416	7,872	939	679
Veterinary institute	6,697	6,998	1,815	4,343
Skopje Healthcare Bureau	63			
Kumanovo Healthcare Bureau	397	447	138	9
Bitola Healthcare Bureau		12		
Ohrid Healthcare Bureau		18		

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 5. Extent of examined samples for quality

Authorised institution	Total	Import	Domestic produce and circulation
Republic Healthcare Bureau	14,426	13,826	600
Veterinary institute	6,796	6,012	784
Bitola Healthcare Bureau	552	279	273
Kumanovo Healthcare Bureau	1,791	1,018	773
Kochani Healthcare Bureau	208	/	208
Ohrid Healthcare Bureau	543	7	536
Prilep Healthcare Bureau	1,148	539	645
Strumica Healthcare Bureau	440	381	59
Skopje Healthcare Bureau	1,408	/	1,408
Tetovo Healthcare Bureau	215	/	215
Veles Healthcare Bureau	403	/	403
Shtip Healthcare Bureau	134	/	134

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 6. Examined samples for quality by groups of foodstuffs

Product group	Total examined	Total unsafe %	Unsafe in import %	Unsafe in domestic produce and circulation %
Milk	680	5.6	0.45	15.6
Dairy products	1,476	3.9	0.0	8.2
Meat	1,166	0.3	0.44	0.0
Meat products	1,367	3.4	0.0	6.7
Fish	51	0.0	0.0	/

Fish products	221	0.0	0.0	/
Eggs	47	17.0	5.7	50.0
Cereals, flour	1,992	2.1	1.8	4.1
Bread, pasta	2,166	3.7	0.09	7.7
Patisseries	2,143	1.4	0.0	8.5
Sugar	2,924	0.5	0.2	5.9
Dietary products and Children's food	692	5.6	5.9	3.6
Fruit	490	4.5	48	/
Vegetables	409	1.5	1.6	/
Fat	1,721	1.1	0.4	9.5
Additives	1,819	2.5	1.8	15.8
Coffee	1,068	0.6	0.5	1.3
Alcoholic beverages	785	1.0	0.3	4.0
Non-alcoholic beverages	2,248	3.2	1.7	5.6
Ice-cream	361	4.9	0.4	16.2
Ready made food	251	2.4	/	6.2
Fruit products	1,272	2.3	2.1	3.4
Vegetable products	931	1.9	0.8	6.7
Spices	393	5.3	0.7	20.0
Cooking salt	619	10.8	8.6	17.1
Other	808	3.2	3.0	5.1
Source and processing: Internal report of the State Sanitary and Health Inspectorate				

Figure 7. Examined additives samples by groups of foodstuffs

Product group	Total	Import	Domestic produce and circulation	Unsafe	
				number	%
Dairy products	198	16	182	0	0.0
Processed meat	1,050	684	366	0	0.0
Grain products	224	74	150	0	0.0
Patisseries	238	174	64	5	2.1
Bonbons, sugar concentrates	420	401	19	12	2.86
Dietary products	140	126	14	0	0.0
Fruit products	954	905	49	24	2.5
Vegetable products	109	103	6	6	5.8
Non-alcoholic beverages	845	496	349	40	4.7
Alcoholic beverages	83	64	19	0	0.0
Source and processing: Internal report of the State Sanitary and Health Inspectorate					

Figure 8. Examined additives parameters

	Total	Unsafe	Import		Domestic produce and circulation	
			Total	Unsafe	Total	Unsafe
Preservatives						
Total RM	2,805	37	2,102	32	703	5
Benzoate, sorbate	2,604	24	1,440	24	624	0
Nitrites	138	0	127	0	11	0
SO2	741	8	535	8	68	0
Food colour						
Total RM	497	37	361	37	136	/
Artificial sweeteners						
Total RM	162	25	148	24	14	/

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 9. Examined samples for preservatives

Group	Total examined	Unsafe	Import		Domestic produce and circulation	
			Total	Unsafe	Total	Unsafe
Dairy products	198	0	182	0	16	0
Processed meat	207	0	126	0	81	0
Pâtisseries	135	5	132	5	3	0
Fat	89	0	81	0	8	0
Non-alcoholic beverages	643	13	336	9	307	4
Alcoholic beverages	77	1	58	0	19	1
Fruit products	924	11	875	11	49	0
Vegetable products	99	6	97	6	2	0

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 10. Extent of examined samples for pesticides and heavy metals

	Pesticides	Heavy metals
Milk	465	469
Dairy products	601	622
Meat	2,162	2,186
Processed meat	437	463
Fish and fish products	327	389
Cereals, flour	1,272	1,316
Bread, pasta	269	583
Confectionery	404	2,434
Dietary food	158	355
Fruit	900	912
Vegetables	651	492
Fruit products	493	563
Vegetable products	197	365
Fat	869	913
Coffee, tea	656	668
Ice-cream	115	115
Additives	145	1,053
Alcoholic beverages	85	407
Non-alcoholic beverages	56	370

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 11. Detected pesticide concentration in foodstuffs

Group	Parameter	Minimum	Maximum	Average	Maximum allowed concentration
Cereals	Malathion	0.0	0.25	0.002	3.0
Vegetables	Lindan	0.0	0.12	0.008	0.1
Vegetables	Ethion	0.0	0.015	0.001	0.1
Vegetable products	Lindan	0.0	0.018	0.001	0.1

Source and processing: Internal report of the State Sanitary and Health Inspectorate



Figure 12. Foodstuffs contamination with heavy metals (mg/kg)

Group	Lead		Cadmium	
	mean value	Maximum allowed concentration	mean value	Maximum allowed concentration
Milk	0.0	0.1	0.0	0.01
Dairy products	0.0	0.4	0.0	0.02
Meat	0.003	0.5	0.0	0.05
Meat products	0.005	1.0	0.0	0.1
Cereals	0.0	0.4	0.0	0.1
Bread, pasta	0.0	0.4	0.0	0.05
Fruit	0.001	1.0	0.0	0.05
Vegetables	0.009	1.0	0.0	0.05
Fruit products	0.001	1.0	0.0	-
Vegetable products	0.006	1.0	0.002	0.05

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 13. Analysed samples for mycotoxins

Group	Total examined	Unsafe	
		Number	%
Milk	5		
Dairy products	49		
Dairy children's food	39		
Meat products	80		
Dried Fruit	407	21	5.2
Dried vegetables	295		
Coffee, cocoa, tea	541	25	4.6
Spice	26		

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 14. Microbiologically tested foodstuffs

	Total number examined	Unsafe	
		Number	%
Total RM	26,695	789	2.96
Imported	15,451	29	0.19
Domestic produce and circulation	11,244	760	6.76
Industrial produce	3,103	77	2.48
Artisan produce	5,580	448	8.03
Circulation	2,561	235	9.18

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 15. Microbiological safety of samples in circulation and of domestic produce

Authorised institution	Industrial produce		Artisan produce		Circulation	
	Total	Unsafe %	Total	Unsafe %	Total	Unsafe %
Republic Healthcare Bureau	157	0.6	238	5.4	21	9.5
Veterinary institute	1,696	0.3	242	0	4	6.8
Healthcare Bureau	1,453	4.6	5,362	8.0	3,698	13.6
Total	3,306	2.2	5,842	7.6	3,993	13.6

Source and processing: Internal report of the State Sanitary and Health Inspectorate

Figure 16. Extent of microbiologically tested foodstuffs			
Authorised institution	Total	Import	Domestic produce and circulation
Republic Healthcare Bureau	7,719	7,235	484
Veterinary institute	8,977	7,985	992
Bitola Healthcare Bureau	933	0	933
Kumanovo Healthcare Bureau	1,966	214	1,752
Kochani Healthcare Bureau	489	0	0
Ohrid Healthcare Bureau	506	10	496
Prilep Healthcare Bureau	791	4	787
Strumica Healthcare Bureau	476	0	476
Skopje Healthcare Bureau	3,296	0	3,296
Tetovo Healthcare Bureau	208	0	208
Veles Healthcare Bureau	808	0	808
Shtip Healthcare Bureau	455	0	455
Source and processing: Internal report of the State Sanitary and Health Inspectorate			

Figure 17. Microbiologically tested foodstuffs groups				
Product group	Import		Domestic produce and circulation	
	Total examined	% Unsafe	Total examined	% Unsafe
Milk	286	0.0	357	6.8
Dairy products	641	0.31	1,293	11.9
Meat	2,496	0.44	447	10.3
Meat products	777	0	1,935	8.5
Fish	232	0	44	2.2
Fish products	216	0	41	0
Grain	1,371	0	310	1.9
Bread	624	0	1,870	1.6
Patisseries	835	0	1,213	10.9
Sugar	1,676	0	286	1.7
Children's food	350	0	59	3.4
Fruit products	563	0	148	0.7
Vegetable products	343	0.3	217	3.2
Fat	930	0	197	5.1
Additives	894	0	57	5.2
Coffee	524	0.76	98	3.0
Non-alcoholic beverages	730	1.1	853	0.9
Ice-cream	48	2.0	360	15.8
Ready made food	88	0.0	819	4.4
Spices	123	0.8	24	0
Source and processing: Internal report of the State Sanitary and Health Inspectorate				

Figure 18. Unsafe foodstuffs for microbiological agent				
Microbiological agent	Import		Domestic produce and circulation	
	Number	% of total unsafe	Number	% of total unsafe
Salmonella	1	3.4	16	3.1
Staphylococcus aureus	0	0	141	27.7
Sulphur clostridium	0	0	12	2.2
Proteus	0	0	78	15.3
Escherichia coli	8	27.6	245	48.2
Yeasts	1	3.4	10	1.9
Moulds	3	10.3	11	2.1

Contaminating bacteria	21	72.4	94	18.5
Source and processing: Internal report of the State Sanitary and Health Inspectorate				

Figure 19. Microbiological agents in products of domestic produce and circulation		
Microbiological agent	Total number of samples with confirmed presence	Most frequent containing products (number)
Salmonella	16	Processed meat 10 Meat 2
Staphylococcus aureus	141	Processed meat 46 Dairy products 22 Ice-cream 20 Patisseries 20
Sulphur clostridium	12	Dairy products 2 Processed meat 4
Proteus	78	Processed meat 35 Dairy products 14
Escherichia coli	245	Dairy products 103 Processed meat 49 Milk 33 Patisseries 17
Contaminating bacteria	94	Patisseries 29 Dairy products 11 Milk 10 Meat 9
Source and processing: Internal report of the State Sanitary and Health Inspectorate		

Figure 20. Iodine stability in cooking salt		
Number	Initial concentration	Concentration after six months
1.	25,4	29,6
2.	25,0	26,9
3.	27,5	28,5
4.	21,1	22,2
5.	21,1	22,1
6.	22,2	20,6
7.	21,1	20,6
8.	24,3	25,3
9.	20,0	19,5
10.	28,5	
11.	23,3	
Source and processing: Internal report of the State Sanitary and Health Inspectorate		

**3. What are the general rules applicable in your country to non-food products? For example, is the marketing of products with a label and instructions written in a foreign language allowed? What particulars must be mentioned on the label of any industrial product intended for sale to consumers? Please describe the current status and the foreseen evolution with a precise timetable.**

According to the Trade Law ("Official Gazette of RM" No. 16/2004) imported products shall be controlled at customs terminals in terms of: declaration, instructions for use in conformity with the product technical requirements, quality of goods in terms of chemical and organoleptic features, quantity, packaging, as well as transporting conditions, which are conditions for clearing the product.

The trader is obliged to provide all these evidence for inspection to the competent inspection authorities.

According to the Consumer Protection Law ("Official Gazette of RM" No. 38/2004), declaration is obligatory for each product and it has to contain at least the following information: the name of the product, i.e. the name under which the product is sold; product composition; method of maintenance; method of use; industrial design, trademark or product label, if considered an important element of the product; date of manufacture and expiry date, if prescribed; the producer's name and main office, and for imported products the name and the main office (full address) of the importer, as well as country of origin; possible danger warning, if any; manufacturer statement on altered product features, composition of parts and accessories, i.e. on the kind of changes and manufacturer statement on the compliance of the product with the prescribed conditions.

In addition to the above information, the declaration must also contain data established with special regulations.

All information in the declaration must be truthful, clearly visible and legible, written in Macedonian language and its Cyrillic alphabet, which does not exclude the parallel use of other languages and signs easily comprehensible to the consumer.

## ***B. Return of unlawfully removed cultural objects***

### **1. Do you have legislation providing for the return of cultural objects unlawfully removed from the territory of an EU Member State?**

The issue of recovering the cultural heritage illegally taken from the territory of another country and currently on the territory of the Republic of Macedonia is regulated uniformly for all countries, including EU member countries. In particular, the subject matter is regulated with the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04). The law was adopted on 09.04.2004 and has been applied since 01.01.2005. It already incorporates adequately the key provisions from Directive 93/7/EEC of 15 March 1993 on the return of cultural objects unlawfully removed from the territory of a Member State.

In addition to this, as regards the subject matter, the valid document for Macedonia is the Convention on measures for prohibiting and preventing the unlawful import, export and transfer of ownership of cultural objects of 14 November 1970 (Official Gazette of SFRY 50/73), adopted by the Republic of Macedonia on the basis of succession (with a notification act of October 1996), with legal effect since 30 April 1997. At the same time, from the same date, regarding the subject matter, but in the event of armed conflict, the following are also relevant for the Republic of Macedonia: The Convention on the Protection of Cultural Property in the Event of Armed Conflict of 14 May 1954 (the 1954 Hague Convention) and its First Protocol of the same date, ratified in the former FNRY in 1955 (Official Gazette of FNRY – International Agreements and Treaties 4/56). Furthermore, an integral part of the Internal legal order of the Republic of Macedonia is considered the Second Protocol of the 1954 Hague Convention for the Protection of Cultural Property in the Event of Armed Conflict of 26 March 1999 ("Official Gazette of RM" 13/02).

The EU member states that have ratified the abovementioned conventions and protocols can, on that basis and according to their provisions, exercise in the Republic of Macedonia the right to recovery of cultural objects unlawfully taken from their territory. EU member states can also exercise this right with the Law on Protection of the Cultural ("Official Gazette of RM" No. 20/04), starting from 1 January 2005, which is in compliance with the respective Directive of the European Union.

## **2. What are the legal provisions ensuring the return of cultural goods, before or after their unlawful removal from the territory of your country?**

The recovery of cultural goods prior to their illegal taking out of the territory of the Republic of Macedonia is exercised on the basis of the general regulations on the protection of property rights and the special regulations for the restitution of movable cultural heritage.

Namely, according to the Law on Ownership and Other Real Rights ("Official Gazette of RM" No. 18/01), the protection of the property right can be exercised, inter alia, by lodging a complaint for return of property (Article 156 paragraph 1), but in that they must prove ownership of the goods they claim, as well as that the goods are in factual possession of the defendant (Article 156 paragraph 2). In accordance with paragraph 3 of that same article, the lodging a complaint for return of property cannot become prescribed.

The return of a movable cultural goods stolen and/or illegally taken from the territory of another country and found on the territory of the Republic of Macedonia shall be exercised according to the provisions of the on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) (Article 100).

In particular, the competent body of claiming country can file their restitution claim either diplomatically or directly to the competent court in the Republic of Macedonia, unless otherwise provided with a law or an international agreement. However, if the competent body of the claiming country has initiated a restitution procedure, i.e. a procedure for return of the goods, against the holder before the competent court in the Republic of Macedonia, they are obliged to notify immediately the Ministry of Culture of the Republic of Macedonia. In that, the restitution claim (complaint) can be filed within 1 (one) year, counting from the day when the claiming country has discovered, i.e. was notified of the place where the goods in question are found and of the identity of its holder, but not longer than 30 (thirty) years from the day when the claimed goods were stolen, i.e. illegally taken from the territory of the claiming country.

As an exception, if it is a matter of movable goods part of a public collection or under special protection of the country of origin, the restitution claim can be filed within 75 years from the day when the claimed goods were stolen or illegally taken (exported). The restitution procedure, i.e. the procedure for return of the cultural goods, before the competent court in the Republic of Macedonia can be initiated if there is evidence: that the goods in question have the status of protected goods according to the regulations of the country claiming restitution and claiming that they were stolen and/or illegally exported from its territory. However, such a procedure cannot be carried out if the export is no longer illegal at the time when the return of the goods was claimed (Article 100 paragraph 8).

The person who has acquired the claimed goods after they were stolen and/or illegally exported, if he/she is a conscientious owner, is entitled to fair compensation on the basis of and in the amount established with a decision of the competent court and after the goods have been returned to the territory of the country of origin (Article 100 paragraph 9). With respect to the rights and obligations of the conscientious and unconscientious holder of the claimed goods, the general regulations apply, i.e. the provisions under Articles 157, 158 and 159 of the Law on Ownership and Other Real Rights ("Official Gazette of RM" No.18/01), precisely stipulating the relationships regarding the rights and obligations of such categories of subjects. In accordance with Article 100 paragraph 10 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04), all expenses concerning the restitution claim and the procedure shall be charged upon the claiming country.

In accordance with Article 100 paragraph 3 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM". No. 20/04) the central authority for coordinating the restitution of the claiming country can request from the Ministry of Culture of the Republic of Macedonia: more accurate identification of the whereabouts of the goods in question in the Republic of Macedonia, as well as a more accurate identification of its owner, i.e. holder; that it enables the authorised persons from the claiming country to carry out, within two months from lodging the restitution claim, the necessary

inspections regarding the claimed goods; to allow the claiming country to cooperate in undertaking measures for the physical protection of the claimed goods etc.

If the movable cultural goods have been stolen and/or illegally taken from the territory of the Republic of Macedonia, action shall be carried out in accordance with Article 100 paragraph 2 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) and the relevant provisions of the ratified international conventions and protocols, as well as in accordance with EU documents.

Namely, in accordance with Article 100 paragraph 2 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04), the Ministry of Culture of the Republic of Macedonia shall: undertake activities for completing the information, records and documents on the cultural heritage dispersed abroad, which can be subject to restitution; file restitution claims to the competent bodies of other countries, in accordance with their regulations and international agreements; cooperate with the central authorities of other countries with a view to coordinate the restitution (recovery) of the goods. At the same time, as a member country to the Convention on measures for prohibiting and preventing the unlawful import, export and transfer of ownership of cultural goods, the Republic of Macedonia is entitled to seek from another country who is a member of that Convention to act pursuant to the provision under Article 7 item (b) sub-item II and Article 13 of the Convention.

Hence, in accordance with Article 7 item (b) sub-item II of the Convention, the Republic of Macedonia can seek seizure and recovery of the goods in question if such a claim has been forwarded diplomatically, substantiated by evidence justifying the same and if the buyer in good faith or the legal owner of the claimed goods is paid fair compensation, as well as customs waiver and other levies for the cultural goods subject to recovery according to that Article of the Convention. In accordance with Article 13 of the Convention, the Republic of Macedonia is entitled to seek from another country which is a member of that Convention, to ensure the cooperation of its competent services in order to facilitate the return of the claimed goods and receive a complaint for return of the respective goods.

In accordance with Article 34 paragraph 1 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04), in the Republic of Macedonia there will be special records on the movable goods whose country of origin is the Republic of Macedonia and are found abroad on any basis and regardless the date of export if such goods present an interest from the point of view of their restitution in the country (dispersed cultural heritage), as well as for the movable goods part of the cultural heritage of another country and found on the territory of the Republic of Macedonia (foreign cultural heritage). The competent body for maintaining the mentioned records is the Administration for Protection of the Cultural Heritage within the Ministry of Culture, which started to operate on 1 January 2005.

### **3. If such legislation exists, what categories of cultural goods are covered?**

The Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) has made official, as key generic terms for identifying the goods under protection, the following expressions: "cultural heritage" and "protected goods".

Furthermore, the following expressions have been designated as specific legal categories: "cultural heritage of particular importance" and "important cultural heritage". In accordance with Article 2 of the Law, the following shall be considered cultural heritage: "...tangible and intangible goods which, as an expression or witness to human creation in the past and in the present or as joint work of man and nature, due to their archaeological, ethnological, historic, art, architectural, urban, ambient, technical, sociological and other scientific or cultural values, features, contents or functions, bear cultural and historic significance and are subject to legal regime for the purpose of their protection and use, in accordance with this and other laws." The respective law establishes 15 types of cultural heritage, with special definitions for each type, classified in three groups (immovable, movable and spiritual cultural heritage). Therein, the movable cultural heritage group defines 9 types of goods, as follows:

- archaeological goods;
- ethnological goods;
- historic goods;

- art goods;
- technical goods;
- archive material;
- library goods;
- cinematheque goods;
- phonotheque goods.

In addition to cultural heritage, the following are also subject of protection, i.e. are treated as protected goods pursuant to the aforementioned law:

- goods under temporary protection: immovable and movable goods for which there are grounds to assume that they present cultural heritage and are protected as provided by Law (Article 30), for which a protection regime for important cultural heritage, i.e. a regime of guaranteed protection is applied;
- protected archaeological zones: restricted areas containing any traces of human existence in the past eras, including places where there are no visible remnants on land or under water, whose excavation and research – in order to protect such material remnants – has been left for future generations (Article 31), for which a protection regime provided for cultural heritage of particular importance, i.e. a regime of special protection is applied.

Cultural heritage of particular importance are those parts of the cultural heritage, i.e. such tangible and intangible goods that have exceptional and other special features. This category of cultural heritage includes two sub-categories: cultural heritage of exceptional importance and cultural heritage of great importance (Article 28). The part of cultural heritage that is not of particular importance presents important cultural heritage (Article 29). Taking into account the legal provisions stated, the conclusion may be drawn that in the Republic of Macedonia, as regards the subject matter, the following fall under the Law:

- designated immovables, i.e. movable goods that present a constituent part of the protected immovable and that can be physically removed or taken out, regardless of the type and category the immovable goods in question fall under;
- movable cultural heritage, regardless of the type and category they fall under, such as individual goods or collections (public or private);
- movable goods under temporary protection, such as individual goods or collections (public or private), regardless of whether they have acquired the status of a protected goods *ex lege* or based on a protection act.

Comparing the legal definitions for the protected goods in the Republic of Macedonia, on one hand, and the definitions of the expression cultural goods under Article 1 of the Convention on measures for prohibiting and preventing the unlawful import, export and transfer of ownership of cultural goods (Paris 1970), Article 1 of the Hague Convention of 1954 and Directive 93/7/EEC, on the other hand, the conclusion may be drawn that the Macedonian protection model has a much wider scope, i.e. covers a wider range of goods than the conventions themselves.

Therefore, for certain kinds and types of cultural goods it is required that they are older than 100 years, and for the greater part of them it is required that they are older than 50 years. On the other hand, as regards goods that are subject to return, Macedonian law does not recognise the expression "national heritage", nor is the possibility to return certain goods limited by the price of the same, as established in the Annex to the Directive.

Consequently, the Macedonian Law allows for the return not only of cultural goods covered with the Directive in question, but it also covers a substantially wider range of protected goods. Such an approach is not excluded by the Directive itself (Article 14 paragraph 1), wherein the possibility has been provided to undertake broader commitments concerning the return of illegally exported cultural goods.

#### 4. Is there a system of licenses, permits etc. for export or import of cultural goods?

The *import, export and taking abroad of cultural goods* are regulated in the Republic of Macedonia with several laws. With respect to *cultural heritage, goods under temporary protection*, with the exception of *archive material*, are also subject to the provisions of the *Law on Protection of the Cultural Heritage* ("Official Gazette of RM" No. 20/04).

The *archive material* and *documentary material* are regulated with the provisions from the *Law on Archives Material* (Official Gazette of SRM 36/90 and Official Gazette of RM 36/95), Regulations in the field for foreign trade operations are also relevant.

##### Import of cultural goods

Concerning import of cultural goods, it must be underlined that the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) establishes a combined protection regime. Such a regime involves:

- *general prohibition on import of stolen cultural heritage* (Article 53): stolen from museums, religious and similar public buildings or institutions on the territory of another country.
- *allowed import of movable cultural heritage* in the form of import pursuant to *the regulations on foreign trade operations*, except in the cases when, according to the regulations of the exporting country, an export license must be provided for import, with an obligation, in both cases, for the *importer* to declare *the imported goods* to *the competent protection institution* within *eight days* from the date of import (Article 99).

The *Law Amending the Criminal Code* ("Official Gazette of RM" 19/04), violating the *general prohibition on import of stolen cultural heritage* is established as a *crime*, punishable according to Article 266-b of the Criminal Code with a prison sentence from one to ten years. According to the *Decision for designating goods as forms of import and export* ("Official Gazette of RM" 58/04), the import of *art goods, collections and antiquities* is under a *free import* regime.

##### Export of cultural goods

The regime for export of cultural goods, laid down in the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04), involves:

- establishing and updating a National Inventory of protected goods whose export would substantially impoverish national cultural heritage (Article 97);
- a general prohibition on exporting cultural heritage of particular importance (Article 52);
- export of movable cultural heritage not covered by a general prohibition scheme, as well as of other protected movable goods, only on the basis of an approval of the Institute for the Protection of Cultural Heritage (Article 97);
- issuing an approval for exporting protected goods: which are subject to international trade or which are permanently transferred to a holder of public collections abroad; which are not listed in the National Inventory relevant for export; or which are listed in that inventory, but are subject to a restitution claim or their export is of public interest pursuant to an international agreement (Article 97);
- adopting a decision for a ban on the export of: protected goods not listed in the National Inventory; and which are not protected, unless a decision for temporary protection is previously adopted (Article 97);
- issuing an export certificate for unprotected antiquities and art or other collection items, whose export is not covered by a free export regime within the meaning of the regulations on foreign trade operations (Article 97);
- informing the public of: cultural heritage whose export is covered by a general prohibition scheme; protected goods listed in the National Inventory relevant for export; and any adopted decision on prohibiting export (Article 97);
- notifying customs authorities of any issued export approval or certificate, as well as of any adopted decision on prohibiting export (Article 98);



- delivering to the customs authorities: a complete file with photographic records on the movable goods whose export is allowed or prohibited; an updated list of movable cultural heritage covered by a general export prohibition scheme; and an updated list of protected goods listed in the National Inventory relevant for export (Article 98).

The export of cultural heritage or goods under temporary protection without a license, i.e. approval, constitutes a crime punishable in accordance with Article 266 of the Criminal Code. A prison sentence of one to ten years is prescribed, and a fine for legal entities.

In accordance with the Decision for designating goods as forms of export and import, the export of art, collection and antiquity objects is under a "D" regime (export based on license, i.e. approval).

### **Taking abroad cultural goods**

The Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) also regulates the issue of exit of protected goods abroad (Article 96). In that sense, the respective provisions prescribe:

- issuing an approval for taking abroad movable cultural heritage and other protected movable goods abroad for the purpose of exhibition, conservation, expertise and other justified cases;
- ensuring a bank deposit in the amount of the value of the protected goods, commercial insurance, guarantee or another kind of obligation of a foreign government, if so required by the authority issuing the approval for taking the goods abroad;
- appointing a deadline for return of the protected goods in the country;
- stipulating specific terms for handling, packing, transport, escort, accommodation, keeping and presenting the protected goods, depending on specific circumstances;
- notification of the authority issuing the approval for taking the goods abroad that the goods in question have been returned in the country within the designated deadline;
- treatment of taking abroad as illegal export in the event that the goods in question are not returned in the country within the designated deadline;
- notifying customs authorities of any issued approval for taking the goods abroad and enclosing a complete file on the goods in question.

In accordance with the Law on Archives Material, the approval for taking abroad archive material is provided by the Government of the Republic of Macedonia upon the proposal of the State Archive of the Republic of Macedonia.

The taking abroad of cultural heritage or goods under temporary protection without a license, i.e. approval, constitutes a crime punishable in accordance with Article 266 of the Criminal Code. The penalties are the same as for illegal export itself.

The control of import, export and taking abroad of cultural goods is within the competence of the Customs Administration of the Republic of Macedonia, while approvals for export and taking abroad of cultural goods are issued by the Institute for the Protection of Cultural Heritage within the Ministry of Culture.

### **5. Which is the central authority, if any, responsible for dealing with the export of cultural goods and ensuring the return of cultural goods?**

The competent body for deciding upon requests for export of cultural goods, where export is not covered by a general prohibition scheme, is the Institute for the Protection of Cultural Heritage, an authority within the Ministry of Culture with the capacity of a legal entity.

*The Institute also decides on requests for taking abroad of protected goods, with the exception of archive material (see answer to question [01 IV B 4](#)). Namely, in accordance with the Law on Archives Material, taking abroad of archive material is decided upon by the Government of the Republic of Macedonia (Article 18).*

The competent authority for control of export, import and transit of goods for which measures for protecting cultural goods have been prescribed pursuant to Article 10 paragraph 1 item 9 of the

Customs Law ("Official Gazette of RM" 46/04) is the Customs Administration of the Republic of Macedonia (see answer to question [25 II 16](#)).

The central authority for coordinating the return of cultural goods is the Ministry of Culture of the Republic of Macedonia. Its competencies in this respect relate both to foreign cultural heritage and to dispersed national cultural heritage (Article 100 paragraphs 2 and 3 of the Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) (- see answer to questions [01 IV B 1](#) and [01 IV B 2](#)).

**6. Do you have any plans to modify the existing legislation? Please give details and timetables.**

The Law on Protection of the Cultural Heritage ("Official Gazette of RM" No. 20/04) is new and its application has started on 1.01.2005, as a primary law in this field. Depending on the needs regarding its implementation, changes to it are possible in terms of further precision and upgrading of the import, export and taking abroad regime for cultural goods regarding the European Union, as well as further precision and designation concerning the obligations and procedures arising from other international agreements ratified by the Republic of Macedonia.

In addition to this, it is projected to adopt in the 2005-2007 period laws to ratify:

- the European Convention on Offences Relating to Cultural Property (Delphi, 1985);
- the Revised European Convention on the Protection of Archaeological Heritage (Malta, 1992);
- the Convention on the Return of Stolen or Illegally Exported Cultural Objects (Rome, 1995).

***C. Control of the acquisition and possession of weapons***

**1. Do you have legislation providing for the control of the acquisition and possession of weapons?**

The Law on Weapons adopted on 25 January 2005 ceased to apply the Law on Acquisition, Possession and Carrying Weapons. This Law stipulates the conditions and procedure of issuing consent for purchase of weapons, ammunition and weapon parts with regard to natural and legal persons and weapon authorization or weapon possession authorization within eight days as from the day of the purchase by the local unit of the Ministry of Interior, competent on the basis of natural person's residence or the seat of the legal entity. This Law, inter alia, stipulates the conditions and procedure regarding withdrawal and annulment of weapon authorization; as well as the procedure with regard to sales of weapons and ammunitions and weapon repair and supervision over keeping, storing, and use and sale of weapons and ammunition with relevance to legal entities.

The text of the Law defines the terms of weapons and implements the provisions with regard to classification of firearms contained in international instruments (short firearms, long firearms, automatic firearms, semi-automatic firearms, repeating firearms, and single-shot firearms).

Pursuant to the Directive 91/477/EEC weapons have been classified in: prohibited to purchase (Category A), weapons which may be purchased on the basis of authorization (Category B), weapons which may be purchased for the needs of hunting and sports, subject to authorization issued under mitigating circumstances (Category C), and weapons to be declared and for which authorization is issued (Category D).

With regard to the ammunition quantity, a distinction is considered between the ammunition quantity intended for weapons smooth-bore barrels and non-smooth-bore barrels.

The text of the Law also stipulates the obligations of the owner or user of the weapon with regard to its handling as well as the prohibition on its carrying in public places.

The cases when weapon authorization or weapon possession authorization shall be withdrawn and annulled are explicitly determined as well as the provisions with regard to handling weapons and ammunition in criminal and misdemeanour procedure.

The issue regarding production, repair and circulation of weapons, ammunition and parts of weapon are systemized in relevant Chapters.

With regard to the transport of weapons and ammunition the Law contains conditions concerning trade companies involved in transport of passengers and goods that may undertake transport of weapons as well as a provision providing that the regulations concerning explosive materials accordingly apply to the transport of ammunitions.

The Law also defines the conditions with regard to establishing and operation of civilian rifle range.

## **2. Is there a legislation laying down the categories of firearms the acquisition and possession of which by private persons is either prohibited or subject to authorisation or declaration?**

The Law on Weapons clearly defines which type of weapon may be purchased by a natural person. Category B – firearms which may be purchased on the basis of authorization:

1. Semi-automatic firearms or repeating short firearms;
2. Single-shot short firearms with centre-fire percussion;
3. Single-shot short firearms whose overall length is less than 28 cm;
4. Semi-automatic long firearms whose magazine and chamber can together hold more than three rounds;
5. Semi-automatic long firearms whose magazine and chamber cannot together hold more than three rounds, where the loading device is removable;
6. Repeating and semi-automatic long firearms with smooth-bore barrels not exceeding 60 cm in length;
7. Semi-automatic firearms for civilian use which resemble weapons with automatic mechanisms;
8. Single-shot long firearms with smooth-bore barrels;
9. Single-shot long firearms with one or more non-smooth-bore barrels;
10. Pneumatic firearms with projectiles energy of 7.5 J and calibre of 4.5 mm;
11. Firearms for industrial purpose.

Category C – firearms that may be purchased on the basis of declaration issued under mitigating conditions:

1. Repeating long firearms other than those listed in category B, point 6;
2. Semi-automatic long firearms other than those in category B, points 4, 5, 6, and 7;
3. Single-shot short firearms with rimfire percussion whose overall length is not less than 28 cm;
4. Pneumatic firearms with projectiles energy of 7.5 J and calibre of 4.5 mm; and
5. Gas firearms for light-sound signalization.

Category D – firearms that has to be declared and are subject to authorization:

1. Cultural and historical firearms;
2. String firearms; and
3. Cold arms.

This Law also details the prohibited firearms, as follows:

Category A – Prohibited firearms:

1. Firearms used as military weapons;
2. Automatic firearms;
3. Firearms disguised as other objects;
4. Firearms with integrated silencer;

5. Firearms with projectiles over 12.7 mm;
6. Explosive firearms and its parts;
7. Gas firearms;
8. Special equipment for firearms;
9. Electric devices;
10. Ammunition with penetrating, explosive or incendiary projectiles, and the projectiles for such ammunition;
11. Pistol and revolver ammunition with expanding projectiles and the projectiles for such ammunition, except in the case of weapons for hunting or for target shooting; and
12. Marking ammunition.

Hunting and sport firearms with optical or sniper target shall not be considered prohibited firearms.

**3. If the legislation is in force:**

**a) Which categories of firearms are covered?**

**b) Which are the conditions necessary to be fulfilled in order to obtain the authorisation?**

**c) What kind of information must be given in the declaration?**

**a)**

The Law on Weapons lists categories and types of weapons that may be purchased, possessed and carried by enterprises and other legal entities, state bodies and citizens, as follows: Category A, Category B, Category C, and Category D. (Detailed in the answer to the previous question in this Chapter)

**b)**

The Law on Weapons lists the general conditions to be fulfilled in case of authorization regarding weapon purchase. Namely, pursuant to this Law:

License regarding weapon purchase to a natural person may be issued on the basis of previously submitted personal written request on issuance of authorization regarding weapon purchase, if the natural person fulfils the following conditions:

1. He/she is over 18 years of age;
2. If he/she has not been withdrawn or limited the business capability;
3. He/she is in a good health capability to possess and carry weapon;
4. He/she is not likely to be a danger to public order;
5. He/she has a justified reason to purchase a weapon;
6. He/she is in possession of technical knowledge concerning standard weapon use, keeping, and handling and knowledge of the weapon rules; and
7. If he/she has a domicile on the territory of the Republic of Macedonia, and in case of a foreigner to be in possession of residence permit on the territory of the Republic of Macedonia, unless determined otherwise with a ratified international agreement.

Weapon purchase authorization of Category C shall be issued to a natural person, who apart from the conditions referred to in points 1, 2, 3, 6, and 7, needs to be an active member of a hunters' or shooting organization and to have certificate on passed hunting exam, or certificate that he/she is an active member of a shooting organization.

**c)**

The request for issuance of weapon purchase authorization shall include the following information: 1. The type of weapon requested for purchase; 2. The purpose for issuance of the weapon purchase authorization; 3. Personal data of the applicant (first name, second name, date and place of birth); residence address, occupation data and company data he/she is employed in, and his/her ID card register number. The applicant, in his/her request for weapon purchase authorization, also provides information whether he/she already possesses a weapon, and the type and number of the weapon authorization.

**4. Are there any special rules for collectors and bodies concerned with the cultural and historical aspects of weapons? If so must these collectors and bodies be recognised by the local authorities?**

The Law on Weapon anticipates special provisions regarding collectors, which regulate the rules and procedures of the weapon collectors. Cultural and historical weapons may be purchased and possessed without a license.

Collectors and other persons who purchase and are in possession of cultural and historical weapons are obliged to declare the weapon in the Republic Bureau for Protection of Cultural Monuments due to the evidence, for which a confirmation is issued.

The Republic Bureau for Protection of Cultural Monuments is obliged to deliver the date regarding the natural person who declares the cultural and historical weapon to the competent body within eight days from the day of the submission.

Carrying cultural and historical weapons and producing, purchasing or possessing ammunition for this type of weapon is not allowed.

Notwithstanding paragraph (1) referred to in this Article, museums may purchase, possess and display, inter alia, cultural and historical weapon to Category A provided for in this Law.

**5. Does the legislation, if any, exclude from its scope weapons and ammunition used for hunting or target shooting? If so, what rules are applied?**

The existing legislation covers hunting weapons, and inter alia, regulates the purchasing procedure, registration, and authorization issuance for possession and carrying hunting weapons, in which scope the submitter is mandatory obliged to submit evidence on being a member of a hunters' organization.

Having regard to the application of target shooting weapons, the Law anticipates special provisions which regulate this matter. Namely, civilian rifle ranges are facilities intended for sports and recreation exercise in shooting as well as training on proper and safe use of weapons, which fulfill the technical and safety conditions for use of firearms, hunting and sport weapons. Civilian rifle ranges may be established by natural and legal persons that apart from the conditions with regard to the entry in the trade registry shall obtain authorization from the Minister of interior. Only natural persons, who, pursuant to this Law or other laws are authorized to carry such weapons or have a special request for weapon purchase, may exercise shooting in rifle ranges.

**If so, what rules are applied?**

This matter is also stipulated in the Law on Hunting ("Official Gazette of RM" No 20/96) whose application is in competence of the Ministry of Agriculture, Forestry and Water Economy.

**6. Do you have any plans to modify the existing legislation? Please give details and timetables.**

The negative trend in the growth of crime in the Republic of Macedonia, including illegal possession of weapons and the increase in the number of committed crimes with elements of violence performed by using firearms that the perpetrators illegally possess, determines the readiness and political will to mobilise all control mechanisms and increase their efficiency in preventing and fighting crime.

In the legislation of the Republic of Macedonia, the acquisition, possession and carrying of weapons was regulated with the Law on Acquisition, Possession and Carrying Weapons (Official Gazette of SRM 25/72, 30/72, 18/76, 25/76, 15/83, 51/88, and Official Gazette of RM 26/93 and 49/03).

The provisions of the existing law were not sufficiently accurate and they did not correspond to the contents of international instruments and legislation in EU member states and their implementation in practise caused difficulties in the work of the competent state authorities.

For those reasons the need was imposed to upgrade and improve national legislation by adopting a Law on Weapons, in which international standards are implemented, as well as the comparative experiences from the West European countries.

The Assembly of the Republic of Macedonia on its session held on 25.01.2005 adopted the new Law on Weapons.

Content-wise, the Law on Weapons is divided into 14 thematic units (chapters): general provisions; acquisition and possession of weapons and ammunition; handling weapons and ammunition; annulment and revocation of the weapon license, the license for possession and the license for carrying; manufacture and repair of weapons and ammunition; trading of weapons, ammunition and weapon parts; transport of weapons and ammunition; civil shooting grounds; transporting weapons and ammunition across the state border; EU citizens; records; supervision; penal provisions and transitory and final provisions.

The new Law on Weapons establishes the subject and scope of its application, excluding application of its provisions to armament and military equipment, as well as weapons and ammunition procured and used for the needs of the Ministry of Defence, the Army of the Republic of Macedonia, the Ministry of Interior, penitentiary and correctional facilities and other state authorities and legal entities as provided with special regulations.

The expression “weapon” has been defined and the provisions for the classification of firearms contained in international instruments (short, long, automatic, semi-automatic, bolt action firearms and single shot firearms) have been implemented. In order to ensure a high degree of efficiency in the implementation of the law, the meaning of certain expression used in this legal text has been established.

In accordance with Directive 91/477/EEC classification has been carried out of weapons prohibited for acquisition (category A), weapons that can be acquired on the basis of an approval (category B), weapons that can be acquired for hunting or sports, on the basis of an approval issued under alleviating circumstances (category C) and weapons that need to be reported and for which a certificate is issued (category D).

Category B and C weapons, weapon parts and ammunition for rifled bore barrels, as well as equipment for hunting and sports weapons may be acquired on the basis of an approval, while ammunition for smooth bore barrels is acquired on the basis of a permit issued for that weapon. The approval is issued by the Ministry of Interior, according to the residence of the person, i.e. the residence of the foreigner in the Republic of Macedonia, i.e. according to the head office of the legal entity, person who has applied, and is valid for six months from the day of issuing the approval.

Up to 100 bullets of ammunition for smooth-bore barrels may be possessed, while for non-smooth and pneumatic bore barrels there is not a limitation. Legal entities registered for securing persons and property or who carry out securing persons and property for their own needs, may possess ammunition for weapons up to 50 bullets for each weapon stated in the license for possession.

One of the essential issues in the legal regulation of control of acquisition of weapons are the requirements that a natural person must meet for issuing a weapons acquisition approval. In accordance with these provisions, a weapons acquisition approval is issued to a natural person on the basis of such personally submitted application if the natural person: is 18 years of age; their contractual capacity has not been revoked or restricted; they physically capable to possess and carry a weapon; they do not present a threat to public order; there is justified reason for acquiring a weapon; they have the technical knowledge for proper use, storage and maintenance of the weapon, are familiar with weapon regulations, have a residence on the territory of the Republic of Macedonia and, if they are foreigners and they have regulated residence on the territory of the Republic of Macedonia, unless otherwise provided with an international agreement. An acquisition approval for a category C weapon is issued to a natural person who, in addition to certain requirements provided by the Law, must be an active member of a hunting or sports association and have passed a hunting examination, i.e. has confirmation that they are an active member of a target-shooting association.

The Law on weapons establishes the conditions under which a weapon acquisition approval is issued to a legal entity on the basis of a previously submitted application. The following conditions have been stipulated: the legal entity must have justified reasons for acquiring weapons for securing persons and property, as well as premises for safe keeping of the weapons, while legal entities acquiring weapons for the protection of persons and property or carry out security of persons and property, must employ full-time persons who satisfy the conditions related to natural persons, provided in this law.

The natural person or legal entity to whom a weapon acquisition approval has been issued is obliged within eight days from the acquisition of the weapon to submit an application to the competent authority for registration of the weapon and issuing a weapon license (for a natural person), i.e. a license for possession (for a legal entity). The weapons license and the license for possession are issued for a term of validity of five years, and for persons older than 65 for a term of validity of three years, with a possibility for extension.

Starting from the generally dangerous nature of weapons, the obligations for the owner or the user of the weapon have been established with respect to handling the same, as well as the prohibition for carrying the weapon in public places, where the places where the use of a weapon may jeopardize people's safety, and pursuant to this law are considered public places, have been defined. The places that are not considered a public place within the meaning of this law have also been designated. The prohibition for carrying and using hunting and sports weapons outside of hunting or shooting grounds has also been laid down.

The new Law stipulates the way of storing weapons and ammunition, actions in the event of missing, losing or theft of the weapon and ammunition, compulsory reporting of found weapons, an obligation to report change of residence, i.e. head office of the holder of the weapon license, i.e. license for possession.

The cases when the weapon license, i.e. license for possession is revoked and annulled are explicitly established, and provisions are contained on the manner of handling weapons and ammunition seized in a criminal or misdemeanour procedure.

The issues of manufacture repair and trading in weapons, ammunition and weapon parts are systematised in special chapters of the Law. The new Law on weapons stipulates that the manufacture of weapons and ammunition and the repair of weapons, i.e. trading in weapons, ammunition and weapon parts may be carried out by trade companies with a head office on the territory of the Republic of Macedonia, who obtain approval for carrying out such activity prior to registration in the Trade Registry. The approval for manufacture of weapons and ammunition and repair of ammunition is issued by the Ministry of Interior following the opinion of the Ministry of Defence and the previous consent of the Ministry of Economy. The approval for trading in weapons, ammunition and weapon parts is issued by the competent authority (the Ministry of Interior) following previous consent of the Ministry of Economy. The law also stipulates requirements that the applicant, the founders and the responsible person in the company must satisfy.

As regards weapons and ammunition transport, there are requirements according to which trade companies that carry out activities for transport of persons and goods may also carry out transport of weapons, as well as a provision that the regulations for transport of explosive materials shall respectively apply to transport of ammunition.

The new Law on weapons introduces civil shooting grounds as facilities intended for sports and recreation in target-shooting, as well as for training for correct and safe use of weapons and the conditions under which the same may be established.

Starting from the complexity of the weapons related matter, special provisions regulate the manner and conditions under which weapons are transported across the state border of the Republic of Macedonia.

The new Law on weapons has provisions for acquisition, possession and carrying of weapons by the citizens of the EU countries that possess European document on weapons. These provisions will apply after the Republic of Macedonia becomes a member of the European Union.

In order to eliminate the possibilities for abuse of authorisations on the part of the persons to whom certain approvals have been issued, the Law establishes an obligation for the Ministry of Interior to maintain records of all issued approvals. Furthermore, it has been established succinctly that the supervision of the provisions of this law shall be carried out by the aforementioned state authority.

In order to efficiently enforce the law, violation, i.e. failure to act pursuant to the provisions of this law is sanctioned, and appropriate sanctions have been established for the perpetrators of established violations.

The transitory and final provisions provide an obligation for companies carrying out manufacture of weapons and ammunition, repair of weapons and trading in weapons, ammunition and weapon parts for which no approval was required until its entry into force, to submit, within thirty days from the date of entry into force of the law, an application for issuing the provided approval.

Licenses for possession and carrying of weapons and licenses for possession issued according to previous regulations must be replaced within one year from the date of entry into force of the secondary legislation regulation on the form of the weapon license, license for possession and license for carrying, and the same shall be replaced if the natural persons, i.e. legal entities satisfy the Law requirements.

#### ***D. Checks for conformity with the rules on product safety in the case of products imported from third countries***

##### **1. Do you have legislation providing for conformity with the rules on product safety in the case of imported products? If so:**

###### **a) Since when has it been in force?**

###### **b) Please describe its broad outlines (which service is responsible for border controls and co-ordination regarding imported products, what is the procedure provided for, etc.?)**

There is no legislation in the Republic of Macedonia fully in compliance with the rules on product safety.

Namely, the Directive 92/59/EEC on general product safety, revised by 95/01/EC is transposed in part in the Consumer Protection Law ("Official Gazette of RM" 38/04). This law incorporates entirely the definitions of "safe product" and "hazardous product", as well as the commitments to provide information and releasing into circulation safe products under these Directives, where domestic and imported products are subject to equal treatment.

The Directive on general product safety must be completely transposed into a new Law on General Product Safety, planned for adoption by the end of 2005.

Furthermore, the Minister of Health must prescribe the Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" No. 54/04).

- general requirements on foodstuff safety, as well as special requirements for the safety of separate types of foodstuffs in accordance with the general requirements for foodstuff safety, and
- general requirements for the safety of products and materials used for packaging or coming into contact with foodstuffs.

The preparation of secondary legislation is underway.

The Minister of agriculture, forestry and water management must prescribe, in accordance with the general safety requirements from the Law on Safety of Foodstuffs and Products and Materials in



Contact with Foodstuffs ("Official Gazette of RM" 54/02), the general requirements for foodstuffs of animal-origin.

**a)**

The Consumer Protection Law is in force since 25 June 2004.

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs ("Official Gazette of RM" 54/02) is in force since 23 July 2002.

**b)**

The competent services for border control of imported products are the following:

1. The State Market Inspectorate, based on the Trade Law ("Official Gazette of RM" 16/04) and the Law on Quality Control of Agricultural Products and Foodstuffs in Foreign Trade ("Official Gazette of RM" 5/98 and 13/99). Prior to commencing the customs procedure the State Market Inspectorate carries out inspection supervision of goods with respect to the declaration and the instructions for use, and it completes a document (minutes) on the basis of which the competent customs authority clears the goods.
2. The State Sanitary and Health Inspectorate is competent for border control of foodstuffs, toys, beauty products, tobacco and tobacco products and general consumption goods.

All importers are obliged to submit an application for health inspection at import to the State Sanitary and Health Inspectorate. Health supervision encompasses: establishing the hygiene conditions in which the shipment has arrived, the hygiene of the vehicles, the micro-climate conditions, time of transport from loading to arrival at the border terminal, organoleptic examination and taking samples for laboratory examination. Following organoleptic examination and taking samples, the State Sanitary and Health Inspectorate issues consent for customs clearance.

1. The Ministry of Agriculture, Forestry and Water Economy, through the Plants Protection Directorate and the State Agricultural Inspectorate, carries out control of shipments at import of plants and plant protection chemicals. The procedures applied are standard according to IPPC and EPPO. The examination system at border terminals is comparable to the acquis and the same consists of inspection of paperwork, identification, sanitary examination of plants (organoleptic examination, taking samples for laboratory analysis, taking measures for plant protection) and document registration.
2. The Ministry of Agriculture, Forestry and Water Economy, through the Veterinary Directorate, carries out veterinary and sanitary check-up and control at the border terminal. Veterinary and sanitary inspection and control of shipments importer, exported and in transit is carried out by a veterinary inspector. Shipments of animals, products, raw material of animal origin and offal, shipments containing ingredients of animal origin, artificial insemination seeds, fertilised ovule and embryos, and cattle feed, stable manure, animal urine, compost and other items that may transmit a contagious disease shall be subject to control in circulation. The procedure consists of filing in an application, inspection of documentation, identification, taking samples for laboratory examination, taking quarantine measures, if necessary, and document registration following the completed inspection.
3. The Customs Administration plays a part in applying regulations in the procedure for importing goods on the basis of the competence established with Article 10 of the Customs Administration Law ("Official Gazette of RM" 46/04). The customs authorities carry out the customs clearance procedure if they are assured that the necessary controls have been carried out by the aforementioned competent services, i.e. if the necessary permits, consents, approvals or attestations from other competent services are attached to the customs declarations.

There is no service in the Republic of Macedonia in charge of border control and coordination of imported products.

## V. PUBLIC PROCUREMENT

### *A. State of legislation in the field of public procurement*

#### **1. Does existing legislation cover all types of contracts? If exclusions are foreseen, on which grounds are they established?**

The regulation in the field of public procurement in the Republic of Macedonia has commenced with the adoption of the Law on Public Procurement by the Assembly of the Republic of Macedonia in June 1998 ("Official Gazette of RM" 26/98). The same has been amended on two occasions: in January 2002 ("Official Gazette of RM" 2/2002) and in April 2003 ("Official Gazette of RM" 24/2003).

The experience from the implementation of the Law on Public Procurement, as well as the need to further align our legislation with that of the EU, have imposed the need for a more profound amendment of this field and adoption of a new law based on European principles and standards.

The new Law on Public Procurement has been adopted by the Assembly of the Republic of Macedonia on 26 March 2004 ("Official Gazette of RM" 19/2004) and the same entered into force on 7 April 2004.

The Law on Public Procurement regulates the manner and procedure for carrying out procurement in the Republic of Macedonia and, at the same time, established a legal framework for the conduct of suppliers and bidders in public procurement.

Public procurement, in accordance with Article 2 paragraph 1 item 2 from the Law on Public Procurement, is a compilation of activities carried out by the supplier and related to the acquisition of goods, obtaining services or carrying out work.

Article 3, 4 and 5 from the Law regulate the exception to the application of the Law on Public Procurement.

In accordance with Article 3 of the Law, the provisions of the Law on Public Procurement shall not apply to public procurement for the defence and security of the country; they are declared a state secret and relate to the purchase of weapons, military equipment and special operations technology, in accordance with law.

The provisions of the Law on Public Procurement, pursuant to Article 4, do not relate to public procurement for which funds from international organisations (donors and creditors) have been provided, if they have prescribed special terms of procurement for the same.

In accordance with Article 5 from the Law, the provisions of the Law on Public Procurement shall also not apply to procurement for:

- purchasing or renting land, buildings or other real property or rights arising thereof, unless their purchase or rent requires ensuring funds (credits or loans);
- financial services for issuing, disposing, purchase or transfer of securities or other financial instruments, broker services and services of the National Bank of the Republic of Macedonia;
- purchase, development, production or co-production of programme materials by radio or television stations and for the time slots for radio and television broadcasting;
- services for speech telephony, telex, radiotelephony, paging and satellite services;
- employment mediation services;
- research and development services, except when the supplier uses the research to commercial ends; and
- granting a concession.

**2. Are all tenders above a certain threshold published before the launching of the procedure? What are the types of information that your legislation requires to be included in notices of invitation to tender?**

In accordance with the Law on Public Procurement, if the value of the procurement exceeds 3,000 euros in denar equivalent value, the purchaser is obliged to carry out the same by applying one of the following kinds of procedures: open invitation, limited invitation, project development competition or limited invitation for consulting services.

The procurement invitation, in accordance with Article 30 paragraph 1 of the Law on Public Procurement, by open invitation, limited invitation, project development competition and limited invitation for consulting services, must compulsorily be published by the purchaser in the Official Gazette of RM.

In accordance with paragraph 3 of this Article, the invitation may be published on the public procurement website of the Public Procurement Bureau without any compensation, within three days following the delivery of the electronic version.

The open invitation announcement, in accordance with Article 57 of the Law, compulsorily contains:

- the name, address and head office of the purchaser, telephone and fax numbers;
- the number of the invitation;
- description of the subject and quantity of procurement;
- place of delivery, performance of work or provision of services;
- a statement of the possibility to divide the procurement into parts, depending on the type of goods, equipment and service;
- the place and conditions for issuing bidding documentation, the amount and mode of payment of the sum to be paid to obtain the documentation;
- the closing date for receiving bids and the address to which bids are sent;
- the persons authorised to take part in opening the bids;
- the date, hour and place of opening the bids;
- the requirements for submitting a contract execution guarantee;
- evidence and documentation that the bidder needs to prove economic and financial, and technical capacity;
- the time of validity of the bid;
- the criteria for selecting a best bid, i.e. for awarding the contract;
- description of the processing of the bid and the form and contents of the bid;
- other information pertaining to the subject of procurement.

The limited invitation announcement, in accordance with Article 61 of the Law, compulsorily contains:

- the name, address and head office of the purchaser, telephone and fax numbers;
- the number of the invitation;
- the intention of the purchaser to carry out a certain type of procurement;
- evidence and documentation that the bidder needs to prove economic and financial, and technical capacity;
- the closing date for receiving bids and the address to which bids are to be sent;
- the minimum criteria on the basis of which the purchase shall assess the capacity to carry out the supply; and
- the deadline for adopting a decision for qualification of the candidates who applied.

**3. Please provide a general description of your existing procurement procedures. Are procuring entities allowed to proceed to negotiations? If so, under what conditions?**

The purchaser, in accordance with Article 29 of the Law on Public Procurement, may conduct public procurement by applying one of the following procedures:

- open invitation;
- limited invitation;

- negotiation procedure;
- project development competition; and
- limited invitation for consulting services.

The open invitation is a procurement procedure where all interested subjects may make a bid in accordance with the previously defined requirements by the purchaser provided in the tender documentation.

The purchaser conducts a limited invitation procedure when on the basis of a limited invitation for the financial and technical capacities of the candidates applied and on the basis of established criteria they select a certain number of candidates who, according to their assessment, would be capable and qualified to carry out the procurement with certainty. Procurement by way of limited invitation is carried out in two phases. In the first phase, the purchaser:

- makes a public invitation to all interested parties to submit applications for participation in the procurement procedure;
- establishes their economic and financial, and technical capacities, and
- selects a sufficient number of eligible candidates in order to ensure real competition, and at least three.

In the second phase the purchaser forwards a written invitation without public announcement to all selected and eligible candidates to make a bid. Only invited candidates may make a bid.

The public procurement procedure by way of negotiation is an exclusive procedure and may be applied only in a limited number of cases provided by the Law on Public Procurement, and upon prior consent by the Public Procurement Bureau. Prior consent is sought by a written request stating the reasons and the explanation for the need of such procurement, evidence for satisfaction of the requirements for applying this mode of procurement, the value of the procurement and other information about the procurement.

Public procurement may be carried out by way of a negotiation procedure without previous publication of a public announcement when:

- after previously conducting two procedures of open or limited invitation there were not a sufficient number of bids or appropriate bids, provided that the tender documentation of these invitations has not been substantially altered;
- due to technical, intellectual or performance reasons or for reasons related to the protection of exclusive rights registered with the Ministry of Economy or the Chamber of Commerce of the Republic of Macedonia, the procurement may be carried out only by a certain service provider or contractor or forwarder;
- due to emergency caused by events that could not have been foreseen by the purchaser and which may be attributed as an omission to the purchaser or due to events (natural disasters, epidemics, communicable diseases or force majeure) that prevent observing the term provided for the open or limited procedure;
- the purchaser must carry out additional deliveries from the first bidder due to partial replacement of the usual goods or installations; extension of existing goods or installations where the change of bidder would oblige the purchaser to purchase materials with different technical features, which would result in incompatibility or disproportionate technical difficulties in work and maintenance;
- due to unforeseen circumstances it is required to carry out the necessary additional work that was not included in the contract under revision or concluded, provided that:
  - the additional work cannot be technically or economically separated from the primary contract without greater difficulties for the purchaser; and
  - the additional work, even though it can be separated from the execution of the primary contract, is necessary for its later stages, i.e. for its execution.

The overall amount of procurements awarded for additional work as referred to in the above indents may not exceed 20% of the amount of the primary contract, and the length of such procurement, as well as of extended procurement must not exceed three years.

The procurement of a project or a plan in the field of physical and urban planning, architecture, civil engineering and data processing is carried out by the purchaser on the basis of a project development competition.

Participation in the competition is anonymous and the number of applied candidates at the competition must ensure real competition and it must not be lower than three.

The project or the plan is selected by an independent jury comprising exclusively natural persons independent of the competition participants and who cannot take part in the competition.

When a special professional qualification is required from competition participants, then at least one third of the jury members must have the same or appropriate professional qualifications as the candidates.

The jury is independent in its decision for selecting the best project on the basis of the competition criteria.

The purchaser shall make known the result of the competition and the information about the participant whose projects has been chosen by announcing it in the public information media.

A limited invitation for consulting services is related to intellectual services (studies, projects, research, examination, experiments, industrial studies and using copyrights), leading towards the selection of the competent candidate in the appropriate field.

The limited invitation for consulting services determines the subject of the services, the requirements (criteria) that candidate authors in the competition must meet etc.

A limited invitation for consulting services is carried out according to the procedures for limited invitation in accordance with the provisions of the Law on Public Procurement.

Bidders for intellectual services attach to the bid projects, studies, works, patents, licenses etc. confirming their competence and ability to carry out the consulting service that is the subject of the procurement.

In the event that consulting services have a degree of confidentiality, they must be designated with the degree of confidentiality and accompanied by security measures.

Bid for consulting services are reviewed by a jury appointed by the purchaser. On third of the jury members shall be external and from the field of the service sought, and they shall have a consulting vote.

The jury may conduct an interview with each bidder for intellectual services, where each bidder/candidate may further detail, complete or alter his/her bid.

The bidder/candidate attaches to the bid a compensation request, i.e. the price of the service, which must be elaborated on and must not be divulged.

The compensation, i.e. the price may be reduced by the purchaser if the service was not provided with sufficient quality.

The jury shall prepare minutes with an elaborated opinion and submit them to the purchaser.

In the course of the year the purchaser may conduct procurement of lesser value to purchase goods, services and work of lesser volume and value up to the amount of 3,000 euro in denar equivalent value, where they need to ensure at least three bids and select the best bid.

The purchaser may conduct procurement of lesser value only once in the course of the year for a certain type or group of goods, services and work.

The purchaser, in accordance with the provisions of the Law on Public Procurement, may negotiate the terms of procurement with the bidders, i.e. with the candidates they have selected, only in the event when the procurement is carried out by way of a negotiation procedure pursuant to Articles 66 and 67 of the Law.

In accordance with Article 8 paragraph 1 of the Law on Public Procurement, any negotiation between the purchaser and the bidder in the open and limited invitation regarding prices and bid alteration is prohibited.

In accordance with paragraph 2 of the above Article, the purchaser may require the bidder to elaborate on the bid, without an option to alter it, where the bidder shall provide such elaboration before the jury and it shall be entered in the minutes.

#### **4. Do you have any local, regional or national preferences schemes? What do they consist of?**

The Law on Public Procurement ("Official Gazette of RM" No.19/2004), does not contain provisions for local, regional or national privileges in conducting public procurement procedures.

Namely, in accordance with Article 2 paragraph 1 item 4 from the Law on Public Procurement, a bidder is any domestic or foreign legal or natural person supplying or providing goods, services and works, who has made a bid.

The purchaser, in accordance with Article 6 paragraph 1 from the Law, provides fair competition, equality and non-discrimination of bidders, transparency and publicity in public procurement.

In accordance with paragraph 2 of the above Article, the purchaser may not discriminate in terms of citizenship of the bidder or the country of origin of the goods.

Furthermore, in accordance with Article 36 paragraph 4 from the Law, in the tender documentation the purchaser may not specify for the subject of procurement the technical features of a specific brand, model or type, origin of manufacturing etc. When the purchaser is not able to describe in the tender documentation the subject of the procurement in a way that the specifications are sufficiently understandable for bidders, stating the elements such as a protected brand, patent, type or manufacturer must be designated with the words "or equivalent".

#### **5. Do you have any plans to modify existing legislation? If so, please give all relevant details and timetables.**

The new Law on Public Procurement was adopted by the Assembly of the Republic of Macedonia on 26 March 2004 ("Official Gazette of RM" No.19/2004), and entered into force on 7 April 2004.

The existing Law on Public Procurement in the Republic of Macedonia incorporates the following EU directives on public procurement, as follows:

- **Council Directive 89/665/EEC** of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts;
- **Council Directive 92/13/EEC** of 25 February 1992 coordinating the laws, regulations and administrative provisions relating to the application of Community rules on the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors;
- **Council Directive 93/36/EEC** of 14 June 1993 coordinating procedures for the award of public supply contracts;
- **Council Directive 93/37/EEC** of 14 June 1993 concerning the coordination of procedures for the award of public works contracts;
- **Council Directive 93/38/EEC** of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors;

Furthermore, the following secondary legislation has been adopted in accordance with the Law on Public Procurement:

- A list establishing the entities subject to the provisions of the Law on Public Procurement ("Official Gazette of RM" 34/2004), adopted on the basis of article 1 paragraph 3 of the Law;
- Rulebook on the form and contents of the annual public procurement plan ("Official Gazette of RM" 33/2004), adopted on the basis of article 11 paragraph 7 of the Law;

- Rulebook on the procedure for opening bids in open invitation and limited invitation and for the form for taking minutes of opening the bids (“Official Gazette of RM” 50/2004), adopted on the basis of article 46 paragraph 4 of the Law;
- Decision on determining equipment, materials and services of defensive and security nature (“Official Gazette of RM” 69/2004) to which the law does not apply, in accordance with Article 3 paragraph 2 of the Law;
- Decision for appointing president, members and their deputies in the Commission for complaints for public procurement (“Official Gazette of RM” 39/98, 72/2000 and 33/2003), adopted on the basis of Article 61 paragraph 1 of the Law;

Other secondary legislation is in preparation, which will help in the implementation of the existing Law and which will be adopted by the end of December 2004, as follows:

- Rulebook on the detailed rules for estimating the value of the procurement, to be adopted on the basis of Article 9 paragraph 2 of the Law.
- Rulebook on the form and contents of the form and on the manner of keeping the purchasers’ registry of conducted procurements, to be adopted on the basis of Article 17 paragraph 5 of the Law.
- Rulebook on the form and contents of the form and on the manner of keeping the single registry, to be adopted on the basis of Article 18 paragraph 3 of the Law.
- Rulebook on the compulsory elements of the tender documentation, to be adopted on the basis of Article 36 paragraph 10 of the Law.
- Methodology for expressing criteria in points, to be adopted on the basis of Article 50 paragraph 5 of the Law.
- **Methodology for expressing criteria in monetary value**, to be adopted on the basis of Article 50 paragraph 5 of the Law.
- **Rulebook on the method, terms and procedure for selecting experts who will examine the regularity of the public procurement procedure**, to be adopted on the basis of Article 93 paragraph 10 of the Law.

Monitoring the implementation of the provisions of the Law on Public Procurement, in accordance with Article 103 paragraph 1 of the Law, is carried out by the Ministry of Finance and the Public Procurement Bureau.

The priority activities that the Ministry of Finance is competent for and which are planned for the ensuing period, must take into consideration the commitments arising from the Stabilisation and Association Agreement with the European Union concerning public procurement, contained in Article 68 paragraph 3 and related to harmonising our legislation with that of the EU and adjusting the work in this field to the European standards. Article 68 of the SAA binds the Republic of Macedonia to set the deadline for approximation of the Law on Public Procurement with the EU directives on public procurement to 5 (five) years, i.e. until April 2006.

Taking into account that two new EU directives concerning public procurement were adopted in March 2004 (2004/17/EC and 2004/18/EC), by April 2006 Republic of Macedonia, in accordance with Article 68 of the SAA, will also need to incorporate these directives in the Law on Public Procurement.

## **B. Structures**

### **1. Who is responsible for managing the various aspects of public procurement policy? What are the tasks and powers of this (these) body (bodies)?**

In accordance with the provision under Article 112 from the Law on Public Procurement (“Official Gazette of RM” No.19/2004), in force since 7 April 2004, the Public Procurement Bureau was established as a national institution that will take care of the development of the public procurement

system, by ensuring **legality, rationality, efficiency and transparency** in carrying out public procurements, encouraging competition and equality among bidders.

The Bureau has the task to:

- put forward proposals for adopting legal and other acts in the field of public procurement;
- to follow and analyse the implementation of the law and other public procurement regulations, the operation of the public procurement system, as well as to initiate changes for its improvement;
- to provide opinions regarding the application of the law and the secondary legislation;
- to provide advice and assistance for purchasers;
- to prepare standard tender documentation and forms for the procedures for open and limited invitation and for the negotiation procedures;
- to keep a unique registry and sub-registries for procurements and purchasers, which will be available to the public through the website for public procurements;
- to ensure full transparency both in terms of publishing an indicative announcement for the public procurements that any purchaser plans to carry out during the year and in terms of their execution, whereby competition will be encouraged; as regards the irregularities established on the basis of information from purchasers on the conducted public procurement procedures, the Bureau notifies the Government of the Republic of Macedonia and the Minister of finance;
- to establish the minimum requirements for the professional qualifications of the persons to carry out professional work for public procurements;
- on the basis of a previously adopted programme it shall carry out education training for persons who will carry out public procurement procedures for the entities that the Law relates to;
- to have international cooperation regarding the public procurement system with international institutions and other foreign entities;
- to issue guides, manuals and a bulleting in order to, on one hand, achieve unified application of public procurement legislation and, on the other hand, enable transparency and encourage competition among bidders, as well as their education.

The accomplishment of a part of these tasks of the Bureau has commenced at the end of September 2004 through the execution of the Public Procurement Bureau project funded by the European Commission, and it will be carried out until May 2006.

## **2. What review procedures are available in the event of an infringement of public procurement rules? When and to whom are they available?**

In the case of violation of the rules on public procurement, legal protection is regulated with the Law on Public Procurement ("Official Gazette of RM" No.19/2004).

Legal protection is provided at all stages of the public procurement procedure in the form of objection to the Public Procurement Commission of the purchaser and appeal to the Appeals Commission for Public Procurement within the Government of the Republic of Macedonia, as well as complaint to the competent basic court following the finality of the decision by the Appeals Commission.

An objection is filed by bidders and persons who have obtained tender documentation who are dissatisfied with the method of work and review and assessment of the bids submitted to the Public Procurement Commission. The objection is submitted within two days from discovering the violation. The Commission reviews the objection and notifies the bidder within three days whether they have accepted or denied it, and the public procurement procedure is halted until such time. If the objection is accepted, the Commission will correct its work, whereas if it is denied, the same shall be submitted to the Appeals Commission for Public Procurement within the Government.

An appeal may be submitted by the bidder if he/she is: dissatisfied with the best bid choice, excluded from the first phase in the limited invitation and excluded in the open invitation, as well as persons who have obtained tender documentation. The appeal is submitted to the Public Procurement Commission in two copies and within 8 days from the day of the receipt of notification. The Public Procurement Commission delivers the appeal to the Appeals Commission for Public Procurement



within the Government and to the Public Procurement Bureau, together with an explanation for the appealed findings and copies of the entire documentation of the public procurement procedure. For the purpose of protecting the interests of bidders and ensuring impartiality in deciding upon appeals, the regularity of public procurement procedures for values exceeding 30,000 euros will be verified by an expert.

The expert is appointed by the Public Procurement Bureau at the request of the bidder. The expert is obliged to prepare, within eight days from the day of submitting the appeal, a written opinion and deliver it to the Appeals Commission, and if the expert deems that the appeal has grounds, they may offer the procedure participants a reconciliation procedure. In the event that no reconciliation agreement is achieved, the documentation and the expert opinion are submitted to the Appeals Commission.

The costs for the revision of the expert are settled by the subjects who requested their engagement, whereas the costs for the reconciliation procedure are charged on both parties equally. The Appeals Commission is obliged, within 15 days from receipt of the appeal, to decide upon the appeal allegations.

Following the finality of the decision by the Appeals Commission, the appellant is entitled to seek protection before a competent basic court.

Supervision of the implementation of the provisions referred to in the Law on Public Procurement is carried out by the Central Internal Audit within the Ministry of Finance and the Public Procurement Bureau.

The Central Internal Audit carries out inspection supervision of: providing procurement funds; implementing procurement procedures; organising authorities for execution of procurements; procurement records; establishing documentation for procurement and contract execution.

The Public Procurement Bureau prepares an annual report on the findings of the supervision and it shall submit it through the Government to the Assembly of the Republic of Macedonia. The annual report contains the number and type of conducted public procurement, the amount and the funds for public procurement, as well as the problems in conducting procurements.

### **3. What bodies (of administrative or judicial character) are responsible for the review procedures in the field of public procurement?**

Supervision of the public procurement procedures is carried out by the Central Internal Audit within the Ministry of Finance.

The Public Procurement Commission of the purchaser is authorised to decide on objections from the participants in the public procurement.

The Appeals Commission for Public Procurement within the Government of the Republic of Macedonia is authorised to decide on objections denied by the Public Procurement Commission, appeals from the participants in the public procurement and appeals on the decision for halting the procurement procedure by the auditor in the Central Internal Audit.

Control of the use of funds for public procurement is carried out by the State Audit Office. Basic courts decide upon appeals on final decisions of the Appeals Commission.

### **4. What powers are conferred on these review bodies?**

The Central Internal Audit is authorised to:

- Issue a decision determining measures and deadlines for removing established irregularities and faults in the implementation of an ongoing procurement;
- Order halting of the initiated procurement procedure if the purchaser has not removed the irregularities and faults pursuant to a previously issued decision;

- If it is established that the violation of the procurement procedure constitutes a misdemeanour or a crime, immediately file a request for initiating a misdemeanour, i.e. criminal procedure.

The Public Procurement Commission is authorised to accept or deny the objection by the bidders and if they decline to forward it to the Appeals Commission for Public Procurement.

The Appeals Commission for Public Procurement within the Government of the Republic of Macedonia receives appeals through the Public Procurement Commission and is authorised to decide on the appeals independently or with the assistance of an expert. In the event that the expert fails to reconcile the parties, the Appeals Commission is authorised within 15 days to:

- Reject the appeal as unfounded;
- Annul the decision for choice of best bid;
- Annul the executed procedure if they establish that the first-degree commission has applied the legal provisions wrongfully.

Following the final decision of the Appeals Commission, the appellant is entitled to seek protection before a competent basic court.

### **C. Publication**

#### **1. Where do entities publish tender notices?**

The manner of publishing the invitation is regulated in the Law on Public Procurement ("Official Gazette of RM" No.19/2004), in Article 30.

The procurement invitation with the procedures established in Article 29 from the Law, i.e. by open invitation, limited invitation, project development competition and limited invitation for consulting services, must compulsorily be published in the Official Gazette within 10 days from the receipt of the invitation in PE Official Gazette of RM.

The invitation may also be published free of charge on the website of the Public Procurement Bureau, within three days following the delivery of the electronic version.

The invitation for procurement of goods and services whose value exceeds 400,000 euros in denar equivalent value and for works whose purchase value exceeds 1,000,000 euros in denar equivalent value, which, in accordance with Article 12 of the Law on Public Procurement is mandatory carried out by international tender, is also published in the Official Journal of the EU and, if necessary, in the official public information media in non-EU countries selected by the purchaser.

In the event of different times of publication of the invitation, the deadline in the invitation published in the Official Gazette of RM shall apply.

#### **2. What is the present situation in relation to publication? Please give some statistics, including the number of notices published.**

The new Law on Public Procurement, based on European principles and standards, was adopted on 26 March 2004 by the Assembly of RM, published in the Official Gazette of the Republic Macedonia No. 19/2004 and entered into force on 7 April 2004.

Following the entry into force of the Law on Public Procurement, public procurement tenders with a procedure for open or limited invitation are carried out through: project development competition and invitation for consulting services are mandatory published in the Official Gazette of RM.

According to the overview for the period since 7 April, i.e. from the entry into force of the Law on Public Procurement and until 30 September, a total of 1,664 tenders, i.e. public procurement invitations were published in the Official Gazette of RM.

According to the types of procedures, the situation with published tenders, i.e. public procurement invitations, for the aforementioned period is the following:

- a total of 1,505 tenders have been published with an open invitation procedure;
- the open invitation procedure was repeated for 124 tenders;
- a total of 29 tenders have been published with a restricted invitation procedure;
- the limited invitation procedure was repeated for 3 tenders;
- 3 tenders have been published with a competition for project development.

#### ***D. Legal framework***

##### **1. Which measures have been taken to adapt your administrative and judicial system to the framework conditions necessary to make the legislation work? Do you plan to take additional measures in this respect?**

In May 2004 a Sector for the Public Procurement System has been established within the Ministry of Finance as a transitory organisation form at the national level before the establishment of the Public Procurement Bureau, in accordance with the Law on Public Procurement ("Official Gazette of RM" No.19/2004).

The establishment of the Public Procurement Bureau is an important step undertaken for adjusting the administrative system necessary for the functioning of the legislation. Within the accomplishment of the Public Procurement Bureau project there are activities underway for identifying the real needs for adequate organisational set-up and appropriate staffing of the Bureau in order to respond to the legally prescribed competencies.

Within the same project, there will be permanent education of civil servants in the Bureau through trainings, participation at seminars and organising workshops. These activities are at the preparation stage. At the next stage, the Public Procurement Bureau, based on a previously developed programme, will carry out training of experts with the purchasers by organising seminars, trainings and workshops.

The adjustment of the IT system of the Bureau will allow not only monitoring the procedures for entities to which the law applies, but statistic and analytic processing of the data from the procurements carried out both at the national level and by separate categories of entities (e.g. budget beneficiaries, budget beneficiary individuals, public enterprises established by the state, public enterprises established by local self-government units, local self-government units etc.).

Bidders may submit objections or appeals at several stages of the public procurement procedure (e.g. to tender documentation, to the work of the Commission in the public opening of the bids, to the decision for selection of best bid, to the decision for selection of best candidates at the first stage of the limited invitation).

After submitting the objection, the Commission of the purchaser, if they consider it justified, may accept it and correct their conduct, and if they consider the objection not justified, they forward it to the Appeals Commission for Public Procurement within the Government of the Republic of Macedonia as an authority in the second instance, which rules on it within three days. In the appeal procedure, the Appeals Commission is obliged, within 15 days from receipt of the appeal, to decide upon the appeal allegations. The decision of the Commission is final.

Following the finality of the decision by the Appeals Commission, the appellant is entitled to initiate court proceedings before the competent basic court.

In accordance with Article 68 of the Stabilisation and Association Agreement with the European Union, by April 2006 the Republic of Macedonia will have to incorporate the two new directives on public procurement (2004/17/EC and 2004/18/EC) in the Law on Public Procurement. This harmonisation of public procurement legislation in the Republic of Macedonia with the European one

assumes adequate adjustment of the administrative system, which will be subject to realisation of the Public Procurement Bureau project.