

CONSUMERS AND HEALTH PROTECTION

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A. GENERAL QUESTIONS

1. Is consumer protection recognised as a specific policy in your country? Are there specific rules on consumer protection in other policy areas?

Yes, consumer policy in the Republic of Macedonia is identified as a specific policy, and it is incorporated in the highest legal act – the Constitution of the Republic of Macedonia, as well as in the separate Consumer Protection Law from 2000 (“Official Gazette of RM” No. 63/00 and 4/02). The activities regarding this policy are an ongoing process, following the experiences from the process of implementation of the Law, and the novelties in the regulation of consumer protection in EU, which has resulted with the adoption of the new Consumer Protection Law in 2004 (“Official Gazette of RM” No. 38/04), see [23 Annex 01](#).

There are specific regulations in the legal system of the Republic of Macedonia in the areas of civil, administrative and criminal legislation, which directly or indirectly apply to consumer protection.

2. Please describe the institutional set-up for consumer affairs in your country.

Consumer protection in the Republic of Macedonia has been institutionalised through the activities of two sectors, one consisting of the State Administrative Bodies and other authorities and institutions of the public sector, and the other consisting of non-governmental organizations with activities directly or indirectly focused on different aspects of consumer protection.

With regard to the first sector, and having in mind the multidisciplinary nature of consumer protection, several authorities and institutions of the administration bodies and the public sector have direct and/or indirect competencies in this domain, which are defined with the Consumer Protection Law (“Official Gazette of RM” No. 38/04), see [23 Annex 01](#), and other laws, as follows:

- Government of the Republic of Macedonia (creation of consumer policy, adoption of Consumer Protection Programme);
- Council for Consumer Protection within the Government of the Republic of Macedonia (proposal of measures and activities, monitoring the implementation of the Consumer Protection Programme, assessment of the market situation, etc.)
- Council for Consumer Protection on the local self-government level (care about consumer protection at a local level).
- Ministry of Economy, with its Unit of Consumer Protection (directly responsible for the implementation of the consumer protection policy, proposes consumer protection programme, takes measures and activities related to the implementation of consumer policy, and harmonises the legislation with the consumer needs);
- State Market Inspectorate, within the Ministry of Economy (control over the implementation of the Consumer Protection Law, assessment of products' and services' quality, protection of consumer economic interests);
- The Courts – in case the consumers initiate procedure;

Besides the Ministry of Economy, the following institutions also have responsibilities for consumer protection: Ministry of Health (State Sanitary and Health Inspectorate and the Bureau of Medicines), Ministry of Agriculture, Forestry and Water Economy (Veterinary Directorate – State Veterinary Inspectorate and the State Agricultural Inspectorate, the Plants Protection Directorate), Ministry of Environment and Physical Planning (State Environment Inspectorate), Ministry of Transport and Communications (Telecommunications Directorate), Ombudsman, Commission for Protection of Competition, Broadcasting Council, Institute for Standardization, Institute for Accreditation etc.

The introduction of the second sector in the consumer protection domain is regulated by the Consumer Protection Law ("Official Gazette of RM" No. 38/04), which in Section VII, Article 2 regulates the rights and obligations of the associations of citizens, established in accordance with the Law on associations of citizens and foundations ("Official Gazette of RM" No. 31/98), in the filed of consumer protection.

The provisions of the Consumer Protection Law (Article 128) provide an array of opportunities for involvement of non-governmental organizations in the consumer policy creation, and in the citizens/consumers information, education and counselling.

3. It should be specified whether there are bodies within the public administration which are competent for:

a) General co-ordination of consumer affairs: is general competence on consumer policy allocated to one designated authority, which is responsible for taking initiatives and for coordinating actions in the consumer area?

b) Market surveillance / general product safety: are there independent administrative structures and enforcement powers monitoring the market for consumer goods, in order to detect breaches of product safety rules and to ensure they are corrected? This would include dealing with consumer complaints and infringement of rules. [Specific questions on product safety and market surveillance are to be found in section C. below.]

c) Market surveillance / protection of economic interests of consumers: are there independent administrative structures and enforcement powers monitoring the market for consumer goods and services, in order to detect breaches of rules protecting the economic interests of consumers and to ensure they are corrected? This would include dealing with consumer complaints and infringement of rules. [See also section D. below.]

Information should outline mandate, responsibilities and powers (e.g. of investigation, to seize the courts, etc.), as well as structure and organisation of the services in charge of consumer policy, including links between central, regional and local level.

Human and financial resources allocated to each sector should be indicated.

Explanations should be provided on how co-ordination between competent authorities is ensured.

a)

The Ministry of Economy is the designated competent body for the implementation of the consumer protection policy; it performs the task of general coordination and is responsible for the actual implementation of the consumer protection policy. The Ministry of Economy takes initiatives and actions in the consumer protection area in accordance with the Consumer Protection Programme and by its own initiative, within its legal scope. The implementation of these activities of the Ministry of Economy is done through the Unit for Consumer Protection.

b)

In the Republic of Macedonia, the monitoring of the market for consumer goods and the detection of breaches of product safety rules are enforced by: State Sanitary and Health Inspectorate, Bureau of Medicines, State Agricultural Inspectorate, State Veterinary Inspectorate - Veterinary Directorate and the State Environment Inspectorate.

The competencies of the State Market Inspectorate also include supervision of the general safety of the products on the market.

State Sanitary and Health Inspectorate, within the consumer protection function, in accordance with its competencies that are further established by specific regulations, performs inspectoral supervision of the enforcement of the laws and regulations regarding the production and sales of: food and food related products and materials, tobacco products, i.e. permissible levels of tar and nicotine, labelling, advertising and warning measures; toys; personal hygiene products, facial and body care products and their packaging; products which come in direct contact with the skin or mucous membranes during their use; narcotics, precursors and poisons .

The State Sanitary and Health Inspector, within its competencies, in cases of detected deficiencies, it is authorised to take measures which include: issuing orders for correction of the found deficiencies;

banning the production, circulation or importation of products, issuing orders for faulty products disposal, etc.

The Food Directorate has been established as a body within the Ministry of Health. The Directorate officially started its work from 01.01.2005. All of the State Sanitary and Health Inspectorate's competencies pertaining to food safety, food related materials and products will be transferred to the Food Directorate. This would provide a new quality of the supervision, which will include import, export, food production and circulation, food related products and materials, and also provide for a greater consumer safety and protection regarding deceptions related to product quality, their production, date of expiry, etc.

In 2003, the Budget of the Republic of Macedonia has funded the activities under the jurisdiction of the State Sanitary and Health Inspectorate with 1.540.000 MKD for material expenses. A total of 42.000.000 MKD has been approved from the Budget of the Republic of Macedonia for funding the start of the Food Directorate activities from 01.01.2005.

The State Sanitary and Health Inspectorate is a part of the Ministry of Health. It consists of 17 regional branches and 1 Border Surveillance Unit which has jurisdiction over the country's border crossings. The Inspectorate is managed by a Director. The State Sanitary and Health Inspectorate employs a total of 95 inspectors.

The State Sanitary and Health inspectors in the regional branches are employed as advisor inspectors and are accountable to the Director, to the Head of Sector, and to the Head of the Unit. By vocation, the advisor inspectors are medical doctors, or specialist medical doctors in preventive medical branches, their responsibilities are distributed by geographic areas, and they are competent for inspection of food, water, contagious diseases, cosmetics, poisons, hospital hygiene, radiation safety, toys, tobacco and tobacco products, air pollution, and noise.

The Professional Operations Sector administers the regional branches. The Sector also includes a Border Surveillance Unit.

The Border Surveillance Unit supervises the safety of imported goods, more specifically: food, toys, tobacco and tobacco products, items for general use, poisons, radioactive substances and passengers in international traffic.

Border surveillance is conducted through 11 regional centres in the Republic of Macedonia, with activities performed on customs terminals and border crossings. 17 inspectors are responsible for the border surveillance.

Bureau of Medicines, being a part of the Ministry of Health, in accordance with the Law on Organisation and Work of the State Administration Bodies ("Official Gazette of RM" No. 58/00 and 44/02) monitors the market of drugs consumption, additional medical products, and medical devices for detection of breaches of the rules for safe, secure and efficient drugs.

The Bureau of Medicines, within its competencies, performs a direct control and supervision of the enforcement of the laws and regulations concerning production, supply and circulation of: drugs, additional medical products and medical devices, takes measures for improvement of conditions, monitors the conditions of supply, production, and circulation of poisons and of their use, monitors the conditions of production, circulation and use of narcotics, participates in the preparation of laws, secondary legislation, programmes, reports, analyses, opinions within the scope of its work, cooperates with other state administration bodies, issues permits for import of drugs, additional medical products and medical devices, issues permits for narcotics and psychotropic substances export and import, issues licenses for retail (pharmacies) and gross sales of drugs, additional medical products and medical devices, issues licenses for production of drugs, additional medical products medical devices, and narcotics. Professional operations include managing of procedures for putting drugs, additional medicines and medical instruments, narcotics, and poisons into circulation. It also cooperates with international institutions in the area of international control of narcotics, psychotropic substances, and precursors.

Professional advisory bodies: The Minister of Health appoints the Drugs Registration, Additional Medicines Registration, and Medical Instruments Registration Commissions. The professional operations bodies (National Laboratory for Drug Control, Centre for Pharmaceutical Information, Centre for Monitoring Undesirable Medicine Side Effects) function as separate institutions at the moment, upon individual authorisations for executing certain activities issued by the Ministry of Health - the Minister.

Within the inspection supervision (regular, extraordinary or special supervision), Bureau of Medicines, through its inspectors, in accordance with its authorisations, undertakes measures against the determined deficiencies which include: issuing orders for correction of determined deficiencies; banning of production or circulation of drugs, additional medical products and medical devices; banning the use of curative substances; stopping clinical drug testing if the pre-conditions prescribed by law are not met; banning the circulation of drugs, additional medical products and medical devices, i.e. certain production series; suggesting withdrawal of drugs, additional medical products and medical devices from circulation; confiscating drugs, additional medical products and medical devices, issuing orders for disposal of faulty products, taking and sending samples of drugs, additional medical products and medical devices for laboratory testing in authorised control laboratory.

The Bureau of Medicines, being a part of the Ministry of Health, according to the organisational structure of the Ministry, consists of the following departments:

- Unit for Medical Procurement of Drugs, Additional Medical Products, Narcotics and Poisons
- Unit for Administrative Affairs;
- Unit for Inspection Supervision ;
- At present, the Bureau of Medicines employs 10 civil servants and a Director.

In 2003, the Budget of the Republic of Macedonia funded the activities under the jurisdiction of the Bureau of Medicines with 3.064.000 MKD for salaries.

The **State Agricultural Inspectorate** performs:

- supervision of the circulation of plants, products, materials and tools, and other tasks determined by law in the area of agriculture during import, export, re-export and transit across the state border;
- survey and control of: agricultural land, agricultural crops and plantations; the breeding and other stock documentation; the premises for processing and finishing agricultural products; the equipment for the same; all the phases of processing and finishing to the final product; the premises for keeping and maintaining agricultural products; the green and cattle markets; the agricultural technical equipment; the way of packaging, labelling and marking; the quality and composition of products; keeping, usage of protection equipment; the prohibition of use and prohibition of use for work; the health properties of products;
- supervision of the total quantities of products from the organic production; of the products of vegetable origin put in circulation and within the scope of the certificates issued by authorised legal entities and institutions; as well as of putting into circulation agricultural production causing harmful effects on people, vegetation and live stock; of visible price list on the products in the market;
- supervision of seeds, seedlings and propagating material put into circulation, if their labels are misleading for the consumers.

The State Agricultural Inspectorate is part of the Ministry of Agriculture, Forestry and Water Economy, and it consists of the following 2 units: Agricultural Inspection Unit and Plants Protection Unit, with the main office at the Ministry, and branch offices in 33 regional branches. The State Agricultural Inspectorate is managed by a Director, and it employs 27 state inspectors.

It is financed from the Budget, through the Ministry of Agriculture, Forestry and Water Economy. In 2003, the Inspectorate spent a total of 9.152.064 MKD for salaries and contributions, but there is no specific data on the material expenses.

The **State Veterinary Inspection**, which is a part of the **Veterinary Directorate**, performs an obligatory veterinary sanitary control and inspection of animals, animal breeding facilities; of animals at fairs, markets, exhibitions, sporting events and other public selling places; of the equipment for production, processing, and finishing; of production and circulation of products, raw materials and waste of animal origin, shops and other places of business selling products of animal origin; of cattle feed; of water used for production and watering of animals; of production of semen for artificial insemination, of ovules and embryos, and their circulation; of drugs for veterinary medicine, veterinary protection and improvement of the environment and nature; of the minimum compulsory health protection of animals against diseases.

The State Veterinary Inspectorate takes and sends samples for laboratory testing in authorised diagnostics laboratory; performs medical examinations of products and raw materials of animal origin, as well as inspections for presence of harmful substances.

The veterinary inspectors perform the veterinary sanitary check-ups and inspections systematically and under previously determined annual programmes in continuity, or on a daily basis, or upon personal initiative, or by consumers report.

The Veterinary Directorate provides guidelines for crisis management in accordance with the Law on Veterinary Health ("Official Gazette of RM" No. 28/98) in cases of crisis occurrence.

Shipments of animals, products, raw materials and waste of animal origin, shipments containing animal origin ingredients, semen for artificial insemination, fertilised ovules and embryos, cattle feed, and other items that can carry communicable diseases during import, export or transit, are subject to veterinary sanitary check-ups and control in the cross border traffic.

The State Veterinary Inspectorate is a part of the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy. The Veterinary Directorate is managed by a Director, and it employs a total of 73 employees, out of which 12 in the main office. The Head of the Unit manages the State Veterinary Inspectorate, and the organisation includes the Unit for Veterinary Inspection on the border crossings with 10 veterinary inspectors and 1 technician on 9 border crossings, as well as the Veterinary Inspection in the internal organisational units with 41 veterinary inspectors and 9 technicians in 21 internal organisational units.

Except for the funds from the common budget of the Ministry for Agriculture, Forestry and Water Economy, which are used for salaries and contributions for the employees, the Veterinary Directorate was allocated 187.000.000 MKD from the 2003 Budget, and 276.150.000 MKD from the 2004 Budget to finance its own activities.

The **State Environment Inspectorate**, in accordance with the Law on Environment and Nature Protection and Promotion ("Official Gazette of RM" No. 13/03 (revised text)), within its competencies, supervises the application of the technical and technological measures for air and water protection against pollution, supervises the protected natural resources, and the measures for protection of the soil against degradation and pollution. In accordance with the Draft Law on Environment, which is currently in a Parliamentary procedure, during the supervision, and within the scope of activity, an Environmental Inspector has the right to:

- determine whether there is production, putting in circulation and usage of certain products and substances prohibited for use because of its negative impact on environment, or to determine the performance of activities and services prohibited for the same reasons;
- determine whether imported technologies, products, semi-products and raw materials which are imported, are banned in the country of origin or the country that exports them for environmental reasons;
- determine whether domestic or imported technology, product, semi-product, or raw material that do not fulfil the prescribed norms for environmental protection are used;
- determine whether products, semi-products, or raw materials which are not labelled properly for pollution or harmful effects on environment are put into circulation;
- determine if there is sale of dangerous chemical substances or products in packages that are not solid, complete or adequate;

- determine if there is advertising, labelling and putting into circulation of products labelled with environmental marks which is not in accordance with the procedures and criteria stipulated in this Law or a regulation adopted on the basis of this Law.

The State Environment Inspectorate employs 9 persons (a Director, and 8 environmental inspectors, 4 of them appointed and authorised for the cities of Veles, Bitola, Strumica and Gostivar).

In 2003, the Budget of the Republic of Macedonia funded the activities under the jurisdiction of the State Environment Inspectorate with 8.000.000 MKD.

According to the functional analysis and the Development Plan of the Ministry of Environment and Physical Planning, the resources of the State Environment Inspectorate shall be enlarged, and the number of inspectors shall be increased to 22.

The obligation for coordinating the activities between the aforementioned inspection bodies and the other institutions and bodies is stipulated by the Law on Organisation and Work of the State Administration Bodies ("Official Gazette of RM" No. 58/00, 44/02).

In accordance with the European Partnership Action Plan for 2005, the following activities are planned:

- Establishing and developing an efficient system for market surveillance;
- Establishment of a coordination body for the market surveillance activities;
- Preparation of an analysis of the current market surveillance system and a restructuring plan.
- Training of entities included in the market surveillance system; and
- Joining RAPEX and RASFF.

c)

The State Market Inspectorate, regarding the protection of economic interests of consumers, performs the market surveillance of goods and services in order to detect violations that harm the economic interests of consumers.

According to the Law on State Market Inspectorate ("Official Gazette of RM" No. 35/97, 23/99, 7/02, 20/02), the State Market Inspectorate monitors: the sales of goods and services, the prices of products and services in production and circulation, the quality of products and services in production and circulation prescribed by standards and regulations, the control of measure units and measuring devices usage in the sales of goods and services, the circulation of goods and services with foreign countries and foreign trade, the sales of valuable metal products, the protection of service marks and trademarks, labels and codes, the quality labels and appellation origin on products, the provision of services, the consumer protection, the catering and tourism industries, the artisanship, and other matters stipulated by law.

Consumers file claims and complaints about purchased products or services through the State Market Inspectorate in writing, or orally, on the free phone 080011333 which covers the territory of the whole country.

The claims and complaints usually relate to putting in circulation of products with expired validity, or to products without declaration or instructions for use written in Macedonian language and its Cyrillic alphabet, or to replacement of mobile phones, electric appliances, shoes, textile products, performed repair services, etc.

After the submitting of claims or complaints by the consumers or by the Macedonian Consumer Organisation, the State Market Inspectors acting upon, determine the actual facts, and in compliance with the Consumer Protection Law in 2004 ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), issue Decisions which order traders to substitute products, or their servicing in order to eliminate the established flaws, or to reduce the price of the faulty product accordingly, etc.

The authority of the State Market Inspectors regarding the inspection supervision and proceedings are stipulated in the Law on Market Inspection and other legislation.

The State Market Inspectorate performs its legally determined activities on the territory of the Republic of Macedonia on central level organised as a single Sector with 5 regional units in the following cities: Skopje, Bitola, Ohrid, Strumica and Stip.

The State Market Inspectorate employs 153 state market inspectors with university degrees.

In 2004, the Budget of the Republic of Macedonia has funded the activities under the jurisdiction of the State Market Inspectorate with 54.477.230 MKD for salaries, and 2.500.000 MKD for goods and services. The State Market Inspectorate has also made some other expenses for goods and services which are incorporated in the budget of the Ministry of Economy. For 2005, the State Market Inspectorate has planned to spend 66.612.000 MKD for salaries and contributions, and 20.000.000 MKD for goods and services and capital expenses.

Within its competencies determined by law, the State Market Inspectorate regularly coordinates its activities with equal or similar bodies competent for market surveillance, such as the State Sanitary and Health Inspectorate, the Veterinary Directorate, the State Labour Inspectorate, the Public Revenue Office, and other bodies and institutions.

The obligation for coordinating the activities of the State Market Inspectorate with the other institutions and bodies is stipulated by the Law on Organisation and Work of the Civil Administration Bodies.

The inspectors survey and conduct the procedures mainly in accordance with the Law on Market Inspection and the Law on General Administrative Procedure ("Official Gazette of SFRJ" No. 52/56, 10/65, 18/65, 32/78, 47/86, 16/86, 4/77, 11/78, 9/86 and "Official Gazette of RM" No. 44/02), stipulating, *inter alia*, that all administrative authorities have the obligation to inform the citizens of the outcome of their claims and complaints.

The State Market Inspector, in accordance with the Consumer Protection Law, has the right to issue administrative orders upon certain activities, to temporarily seize products, and is bound to initiate misdemeanour court proceedings for activities that are determined to be misdemeanour.

Under the Law on Courts ("Official Gazette of RM" No. 36/95, 45/95 and 64/03), the first instance courts in the Republic of Macedonia are authorised to rule decisions for confiscating the temporary confiscated and seized products dangerous to the health and the environment, in accordance with the provisions of the Law on Executive Procedure ("Official Gazette of RM" No. 53/97, 59/00, and 64/03).

4. Have consultation structures or procedures been established in order to allow consumer interests to be represented in discussions on consumer policy, when drafting and implementing legislation?

The Consumer Protection Council within the Government of the Republic of Macedonia, in compliance with the authorities granted by the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), with regard to initiatives and proposals for changing and amending the legislation in the area of consumer protection, brings forth its own proposals and opinions, takes part in discussions and delivers opinions during the adoption of the laws, raises initiatives for amending and appending the legislation in the area of consumer protection, etc.

During the creation of consumer protection policy, and drafting and implementing laws, Consumers' Associations have a significant role, i.e. they submit initiatives and deliver opinions to competent bodies for regulating certain issues in the area of consumer protection policy. In addition, they have the right to consider the consumer's complaints and to consult their members for legal inquiries concerning the legislation applicable to consumer protection and exercising of consumer rights.

The adoption and the implementation of the Consumer Protection Law will provide for the consumers' interests to be included in the creation of the consumer protection policy by inclusion of members of

the Consumers' Associations in the Council for Consumer Protection in order to establish a higher level of consumer protection and clear and efficient legal system supported by institutions that will work on the exercise of consumer interests.

The efforts aimed at inclusion and representation of consumer views and opinions have started to effectuate in certain bodies on the level of line ministries, where the Macedonian Consumer Organisation and other non-governmental organisations are represented. Those bodies include: the Codex Alimentarius Commission, the National Food and Diet Committee, the Committee for Iodine Deficiency of the Republic of Macedonia, the Committee for Fight Against Smoking, the Broadcasting Council, the Committee for Environmental Labelling, and others.

5. Access to justice: which measures are in place, if any, to facilitate consumers' access to justice through the courts to seek individual redress? Are there measures to simplify and speed up small claims litigation? Do out-of-court bodies exist which provide alternative dispute resolution systems (e.g. mediation or conciliation systems)?

There are no specific provisions on measures and procedures relating exclusively to consumers in the Law on Civil Procedure ("Official Gazette of RM" No. 33/98 and 44/02), which would facilitate their access to courts for seeking individual redress. However, this Law provides for initiation of simplified litigation suits for small scale claims that do not exceed the amount of 30.000 MKD. Litigations that include non-monetary claims, where the plaintiff agrees to accept a monetary compensation not exceeding the amount of 30.000 MKD, also fall into the category of small scale claims. Likewise, litigations that include non-monetary claims, where the plaintiff does not demand a reimbursement, but compensation in a form of a movable object with a value of less than 30.000 MKD, also fall into the category of small scale claims.

In principle, the general rules of the Law on Civil Procedure apply to the small scale claims litigations, unless there are specific provisions that determine the court proceedings differently.

The provisions for small scale claims litigations usually provide for quicker court proceedings and resolution of litigants' claims. The proceedings for small scale claims litigations allow for appeals only against the decision for proceedings termination, and the verdict or decision for proceedings termination may be rebutted only on the grounds of serious violations of the provisions on litigation procedures referred to in Article 340, paragraph 2 and wrongful application of substantive law.

The new Law on Civil Procedure, which is in the Parliamentary procedure, with its Articles 433 and 434 determines that the provisions for preparatory hearing do not apply for small scale claims litigations.

If the plaintiff does not appear in court for the first, or any other hearing, and they have been properly summoned, the lawsuit will be deemed to be withdrawn, unless the defendant has been engaged in a discussion at that particular hearing.

In the summon for the main hearing, the disclaimers warn that if the plaintiff fails to appear at court at any of the hearings, the lawsuit will be deemed to be withdrawn; that the litigants are obliged to present all the facts and evidence during the first appearance at court, at the main hearing; and that the decision may be rebutted only on the grounds of serious violations of the provisions on litigation procedures, and wrongful application of substantive law.

The verdict from the proceedings in the small scale claims litigations is proclaimed right after the conclusion of the main hearing.

The Law on Courts ("Official Gazette of RM" No. 36/95, 45/95 and 64/03) allows for equal access to justice to all citizens and forbids bringing decisions that do not comply with the legal provisions and regulations.

In principle, every citizen has the right to demand compensation through a litigation procedure, in accordance with the Law on Obligations ("Official Gazette of RM" No. 18/01, 4/02, and 5/03) and the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), in case the citizen could not exercise his/her right through the authorised inspection bodies.

However, the basic rights of consumers relating to advertising, requests for ban cancellation and illegal advertising, protection from unsafe products, putting into circulation of unsafe toys, putting defective products into circulation and their rights relating to incompatibility, elimination of flaws during the warranty period, revision of prices, as well as substitution with other products, are regulated with the consumer right for claims to the competent State Market Inspectorate and to the other aforementioned inspection services for administrative procedure, which does not exclude the possibility for filing compensation claims before a competent court.

On the basis of the Consumer Protection Law, consumers' associations help the consumers, or a limited number of consumers, with filing lawsuits before competent courts for protection of their rights. Consumers' associations may intermediate in consumer disputes between traders and consumers relating to bought products or services.

There are still no out-of-court bodies in the Republic of Macedonia to allow for alternative dispute resolution. There is a plan for adoption a Law on Mediation, which would include out-of-court dispute resolution, regulating cases and different forms of mediation and conciliation and arbitrary dispute resolution, as well as the legal consequences of the acts and decisions brought during such out-of-court proceedings. This law will be adopted in 3 years time.

6. Has the government drawn up any education, information and awareness-raising programme on consumer issues, which would help consumers be aware of their rights and able to exercise them?

Article 129 of the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), stipulates inclusion of basic knowledge about consumer obligations, rights and protection in the preschool institution programmes, and school programmes for the primary and secondary education.

The primary and secondary schools implement the experimental "Youth Economic Education" programme. This programme has been implemented since the academic year 1997/1998 as a complementary programme in 24 schools with 28 groups from 1st to 8th grade, and in 16 secondary schools with 17 groups. There is a constant interest in a greater inclusion of students in this programme by extending the number of participating primary and secondary schools. For the purpose of this programme implementation, modern educational and teaching tools and expendable materials were provided for every school, and training seminars were organised for the teaching staff.

Similar to that, consumer protection contents is included in the vocational education, within the optional subject Business and Economics in the new curricula for the reformed educational profiles (Economic Assistant, Business Secretary, and Trade and Marketing Assistant) in the economic, law and trade professions.

On the level of University education, the Faculty of Economics has included issues related to the consumer behaviour and protection in the subject programme of the Basis of Marketing studies since 1970, and the Marketing Department, with the acceptance of the ECTS (European Credit Transfer System) programme in the academic 1998/99, studies this subject matter within the subject program of Consumer Behaviour.

At the same time, some activities related to the education of the teaching staff in the domain of consumer protection have been implemented. For example, the Promotion of Consumer Protection in the Republic of Macedonia Programme was carried out through the German Association for Technical Cooperation (GTZ). During the school year 2002, the Macedonian Consumer Organisation, supported by the international consumer protection organisation Consumers International and the Federation of German Consumer Organisations, in cooperation with the Ministry of Education and Science, completed the following activities:

- An Expert study on the possibilities for inclusion of topics on protection of the rights of the children as consumers in the teaching programmes in the preschool and primary education was prepared.

- A Forum was organised, on the Possibilities for Consumer Education in the Educational System. The basic goal of this forum was building a Strategy for Education of Youth as Consumers.
- A workshop was organised, on the Concept Development for Implementation of Consumer Education in the Macedonian Educational System, with the aim to consider the possibilities for developing a common concept for consumer education by all the relevant factors.

Within this project, with the financial aid of Consumers International, picture books for preschool children and a brochure for primary school students were published; and preparations have started for publishing of a Teacher's Handbook with Teaching-technical Aids for the needs of the teachers.

7. Do non-governmental organisations representing consumer interests exist in your country? If so, please describe their situation: how many are there? When were they created? How is their membership composed? Are they representative of consumer interests at national level? Is the government promoting and assisting their development? What are their objectives? Which kind of activities do they carry out? What are their main sources of financing? How many staff do they employ?

Two non-governmental organizations representing the consumer interests have been registered in the Republic of Macedonia, namely the Macedonian Consumer Organisation and the Club of Associations of Citizens - Consumers.

At the moment, the Macedonian Consumer Organisation in Skopje is more active, and it has been recognised internationally as a full member of Consumers International and a member of BEUC – the European Consumers' Organisation. This organisation has been established in accordance with the Law on Associations of Citizens and Foundations ("Official Gazette of RM" No. 31/98)

This Organisation is active in the following fields:

- Taking initiatives aimed at improving the legislation in the Republic of Macedonia in the area of consumer protection;
- Raising public awareness through education, information, counselling, and representing consumer interests;
- Representing consumer interests on local, national and international level and supporting the development of institutions and mechanisms for consumers' protection;

The Macedonian Consumer Organisation is organised to work through a Head Office and a network of branches and Counselling Bureaus for the consumers. There are Counselling Bureaus in the cities of Skopje, Bitola, Tetovo, Stip and Ohrid. This structure allows for gradual expansion of activities through the whole territory of the Republic of Macedonia, with the aim to help the consumers through their education and with regard to their rights exercising.

The Programme of the Macedonian Consumer Organisation follows the guidelines of the workgroups in the following domains:

- Improving the legislation;
- Diet;
- Housing and residence;
- Energy;
- Medical patients' rights;
- Protection of children as consumers; and
- Financial services.

Within these areas, a great number of seminars, round tables, individual researches and media presentations are constantly held with the aim to inform the public about the relevant problems of the citizens.

The organisation publishes its own bulletin “Потрошувач” (Consumer) and a number of educational brochures, and has also organised information systems, so called “Infoteques”, in the legal, diet, housing, health, and financial services areas, as well as an infoteque in the area of household appliances with tables containing comparative tests of these products.

The Macedonian Consumer Organisation played an important role in the promotion of the UN Guidelines for Consumer Protection on the national level, especially during the lobbying for the preparation and adoption of the first Consumer Protection Law in July 2000, and at the same time actively participated in the preparations for the new Consumer Protection Law in 2004.

The Macedonian Consumer Organisation is financed through foreign projects and from the budgetary funds intended for citizens' associations.

The Macedonian Consumer Organisation has implemented a GTZ project for assisting the organisation of consumers in Macedonia in the period 1998 - 2005, on the basis of a bilateral agreement between the German and the Macedonian Government through which an intensive cooperation with the Federation of German Consumer Organisations in Berlin (VZBV) has taken place in terms of gathering knowledge and new experiences with the aim of transferring and adapting them to our specific circumstances and improving the customers' situation. The project has been implemented within the framework of the Economic and Social Development Programme, and the holder of the project is the Ministry of Economy. The aim of the project is to establish a functional system of consumers' interests protection in the Republic of Macedonia. The project will end in 2005, and the Ministry of Economy has applied for a new GTZ project and for support from the CARDS Programme, which was approved during the consultative negotiations. The Macedonian Consumer Organisation will participate in the implementation of the goals and activities in cooperation with the line ministries, the institutions, and the competent inspection services.

The Consumer Protection Law (“Official Gazette of RM” No. 38/04), see [23 Annex 01](#), provides for allocation of funds for information, counselling and education of consumers through a Consumer Protection Programme, and these activities will be implemented through non-governmental organisations for consumer protection, enjoying credibility, national character and international recognition.

The Macedonian Consumer Organisation employs seven full time employees. The number of part time associates, which are engaged when needed, is over 15.

Apart from these two non-governmental organizations, there are also other citizens' associations in the Republic of Macedonia that indirectly protect the consumer interests, namely, the Macedonian marketing association “Marketing” in Skopje, all the environmental associations, etc.

8. Have you developed any relations with other countries on consumer protection issues (e.g. cross-border co-operation activities, exchange of information and best practices, etc.)?

The Republic of Macedonia has started establishing contacts in the area of consumer protection with other countries (Albania, Germany, France, Czech Republic, Slovakia, and Slovenia). There are plans to expand this cooperation with other countries, especially with the countries from the region.

The Macedonian Consumer Organisation, as a full member of Consumers International – the International Consumers Organisation, and a member of BEUC – the European Consumers' Organisation, maintains contacts and carries out project activities with consumer organisations in other countries (VZBV in Germany, Consumentenbond in the Netherlands, the National British Consumers Council, Consumers Association UK, the Slovenian consumers organisation “Zveza potrošnikov Slovenije”, the Consumers Defence Association of the Czech Republic – SOS), as well as with the consumer organisations in the region (in Albania, Romania, Bulgaria, Croatia, Serbia, and Montenegro).

B. LEGISLATIVE FRAMEWORK

1. Please describe the scope of your consumer protection policy. Indicate whether the following sectors are covered and to what extent they are in line with the relevant EC acquis:

a) Safety-related measures:

i) general product safety (Directive 92/59/EEC and revised Directive 2001/95/EC) (see below)

The general product safety Directive 92/59/EEC and revised Directive 2001/95/EC are partially implemented in the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), and the definitions of the terms "safe product" (Article 33) and "dangerous product" (Article 34) have been accepted, as well as the obligation for giving information on the products and putting into circulation of safe products (Article 35).

The Directive 92/59/EEU and revised Directive 2001/95/EU will be fully transposed into the Law on General Product Safety, which is in preparation, and its passing is expected in 2005.

ii) liability for defective products (Directive 85/374/EEC)

(1) Do you have legislation concerning liability for defective products?

(2) Are there legal provisions in force establishing the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product? If such provisions are in force, is there a rule of joint liability in cases where more than one person is liable for the same damage?

(3) If legal provisions on product liability are in force, what products do they cover? Are some products excluded from the scope of these rules? What is the definition of "damage"?

(4) If legal provisions on product liability are in force, how is the producer defined, what are the rules applicable to burden of proof?

(5) If legal provisions on product liability are in force, are there any rules exempting the producer from liability (e.g. producer did not put the product into circulation, the defect causing the damage came into being after the product was put into circulation by the producer, the product was not manufactured for profit making sale, the product was neither manufactured nor distributed in the course of producer's business, the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered, the defect is due to compliance of the product with mandatory regulations issued by the public authorities)?

(6) If legal provisions on product liability are in force, is the producer's liability altered when the damage is caused both by a defect in the product and by an act or omission of a third party?

(7) If legal provisions on product liability are in force, are there any rules on expiration of liability?

(8) Do you have any plans to modify the existing legislation? Please give details and timetables.

(1)

Yes, under the Law on Obligations ("Official Gazette of RM" No. 18/01, 4/02 and 5/03) and the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#).

Article 165, paragraph 1 of the Law on Obligations stipulates that a party trading goods of its own production, which due to flaws of which the party was not aware, presents danger of damage to persons or objects, shall be liable for any eventual damage caused by that defect. According to paragraph 2 of this Article, the producer shall be also liable for any dangerous features of the product

after failing to take all measures necessary to prevent the damage they have been able to foresee by means of warning, safety packing or other appropriate measure.

The Consumer Protection Law regulates the liability of the producer and the distributor for putting defective products into circulation.

Article 41 of the Consumer Protection Law stipulates that the producer, i.e. the distributor, is liable for the damage that has been caused by the defects of their product.

This subject matter is harmonised and regulated in compliance with the Directive 85/374/EEC.

(2)

The liability of the producer for the damage caused by defective products (Article 165 of the Law on Obligations, "Official Gazette of RM" No. 18/01, 4/02 and 5/03) is an objective liability, which means that the guilt of the producer for the damage caused is not relevant for the existence of their liability, but the liability is based on the fact that a defective product has been put into circulation, and it has caused damage. The provision of Article 41 of the Consumer Protection Law also refers to this matter, determining joint liability of the producer and the person that within its business activities on the territory of the Republic of Macedonia imported a product for sale, hire, lease, or some other kind of distribution. The distributor, or the trader, of the product that caused the damage will be regarded as producer, according to paragraph 3 of this Article, if the producer of the product produced on the territory of the Republic of Macedonia cannot be identified, unless the distributor, or the trader, have informed the injured party about the identity of the producer in a reasonable period, or when the importer of the product imported from abroad could not have been identified even though the name of the producer is given on the product itself, unless the distributor, or the trader, have informed the injured party about the identity of the producer in a reasonable period.

The provision of paragraph 4 of Article 41 of the Consumer Protection Law is more precise in relation to objective liability, since it determines the following: if it cannot be determined who the producer or the importer of the product is, then any trader or distributor shall be considered a producer and shall be liable for the damage caused by the defects of the product; and the provision of paragraph 5 of this Article determines that the trader shall be liable to the consumer for any defect related to the conformity, which existed at the time when the products were delivered.

At the same time, it is pointed out that the liability of the producer for the dangerous features of the product (Article 165, paragraph 2 of the Law on Obligations) is also causal because it is sufficient that the defective product has been put into circulation without an appropriate indication about the danger and the need for taking other measures for eliminating the harmful effects during the usage of the product, so the producer is liable if the damage has occurred irrespective of the guilt or innocence for the defect in question. Although this Article determines the joint liability of several producers for the damage caused by a defective product, these cases are covered by the provisions of Articles 195 to 197 of the Law on Obligations for joint liability for the occurred damage.

(3)

The provisions of the Consumer Protection Law (Article 41), as well as the Law on Obligations (Article 165), related to damage caused by a defective product are not limited to specific types of products, and they consider all products put into circulation.

Article 142 of the Law on Obligations defines "damage" as reduction of one's property (ordinary damage) preventing accrual thereof (loss of earnings), and inflicting of physical or mental distress or fear (non-material damage).

This is also covered by the provisions on compensation of material damage included in the Law on Obligations, Articles 174 to 177, the provisions on the scope of compensation for material damage of Articles 178 to 181; more specifically on the compensation for material damage in case of death, bodily or health injury regulated by Articles 182 to 186, and specifically on compensation of material damage in cases of offences to honour and spreading untrue allegations regulated by Article 187, while the compensation for non-material damage is regulated by Articles 188 to 194.

(4)

According to the Consumer Protection Law (Article 4), “producer” is any person that makes final products or components for making basic products; or persons that, through their business name and their designation of the product present themselves as producers. The importer of the product is also considered a producer.

The Consumer Protection Law determines specifically what is considered a safe product in Article 33, and dangerous products are specifically defined in Article 34; they serve as legal provisions for proving defectiveness of products. In this context, Article 42 of the same Law provides that a person should prove that a product is unsafe by means of presenting the product and the time it was put into circulation; and that the product does not meet the general obligation of conformity laid down in Article 22 of this Law or the contractual obligations.

The competent inspection bodies identify the factual situation inspecting the scene, or examining the product with laboratory or forensic analyses.

According to Article 41 of the Consumer Protection Law, the producer is liable for the damage caused by the defects of their product, which means that the producer is liable for the damage provided that the product is put into circulation, and article 47 of the Law prohibits the sale of products with expired period of use.

(5)

According to Article 52, paragraph 1 of the Consumer Protection Law, the producer shall not be liable for the defects of the product if it is proven that:

- They did not put the product into circulation;
- Taking into account the circumstances of the case, it is probable that the defect which caused the damage did not exist at the time when they put the product into circulation, or that such defect came into being afterwards;
- They did not produce the product for sale or for any form of distribution for economic purposes, neither did they produce nor distribute the product in the course of their business venture or their regular operation.
- The defect is due to compliance of the product with mandatory regulations adopted by competent state bodies;
- They made only the component part of the product, or they supplied only the raw materials, supporting materials or additives, so the defect occurred due to the composition of the product in which the component part was incorporated, and the damage resulted from violation of the instructions given by the producer of that product.

Article 52, paragraph 2 determines that a product is not considered defective solely because a better product has been subsequently placed on the market.

(6)

According to Article 52, paragraph 3 of the Consumer Protection Law, the liability of the producer may be limited or excluded when, having taken into account all the circumstances, the damage is caused both by the defect and by the fault of the injured party or any other person for whom the injured party is liable. This means that the producer is partially excluded from liability if the damage is caused by fault of the injured or a third party.

(7)

Article 52, paragraph 5 of the Consumer Protection Law determines that the grounds for producer’s liability shall be limited to a period of 10 years from the date on which the producer put the product that caused the damage into circulation, unless the injured party has in the meantime initiated procedure against the producer.

(8)

There are plans for adoption a separate Law on General Product Safety in 2005, which will regulate the issues covered by Directive 92/59/EEC, revised by Directive 2001/95/EC.

b) Non-safety related measures (protection of economic interests of consumers):

i) misleading advertising (Directive 84/450/EEC)

Directive 84/450/EEC, related to misleading advertising, is fully implemented in the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#). The provisions of this Law (Articles 26 and 27), other than the prohibition of misleading advertising, also prohibit advertising that discredits human dignity, and causes or might cause physical, mental or other damage to children, that to children spread messages or parts of messages that take advantage or misuse or likely to misuse their impetuous nature and lack of experience. At the same time, the Law also regulates cases in which comparative advertising is permitted (Article 29), as well as the requests for termination or prohibition of non-permitted advertising (Articles 29 and 30).

Article 136 of the Consumer Protection Law determines that: A legal entity shall be fined for an infraction with the amount of 100.000 to 300.000 MKD if it acts contrary to the provisions laid down in Article 27, paragraphs 1 and 3 of this Law, and Article 29 of this Law, and in addition to the fine, the legal entity shall be imposed a safety measure - prohibition of performing the activity for a period of two to four years. Apart from the legal entity, the responsible person of the legal entity shall be fined for the infraction with an amount of 20.000 to 50.000 MKD, and it shall be imposed a safety measure – prohibition of performing responsible duty for a period of three months to one year. In case the legal entity does not act in accordance with Article 29 of the Consumer Protection Law, a safety measure - confiscation or temporarily confiscated of products - shall be imposed.

The Broadcasting Law ("Official Gazette of RM" No. 20/97 and 70/03), in its Article 49 states that advertisements should be real and honest, not manipulating the general audience and not adverse to the interests of consumers or users of services. (for more details see the answer under c point i)

The Law on Obligations ("Official Gazette of RM" No. 18/01, 4/02, and 5/03), in its Article 187 determines that a person that has offended the honour of another person or has made untrue statements of the past, knowledge and capability or of something else related to another person, while they have been or have had to be aware that the statements were not true, and has caused physical damage to that person, is obliged to reimburse that person for the damage.

ii) contracts negotiated away from business premises (Directive 85/577/EEC)

Directive 85/577/EEC is fully implemented in the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), with the provisions of Articles 105 to 107, which determine which contracts are considered concluded away from business premises, and they also determine the contracts to which these provisions shall not apply. There are also provisions on the obligation for notification on termination of a contract, which determine that in case of conclusion of a contract between a trader and a consumer away from the business premises of the trader, the trader is obliged to notify the customer in writing about his/her right to unilaterally terminate the contract with a simple statement within a period not shorter than 7 days from the day when the contract was concluded. The trader is obliged to notify the consumer in writing about the address on which they can send the notice on termination of the contract.

According to Article 138 of the Consumer Protection Law, the legal entity shall be fined for infraction with the amount from 80.000 to 240.000 MKD if it concluded a contract according to Article 105, paragraph 1, line 1 and 2 of this Law without legitimising with an identification card (Article 105, paragraph 3). In addition to the fine, the legal entity shall also be imposed a safety measure – prohibition of performing activity for a period from two to four years. The responsible person of the

legal entity shall be fined for the infraction with an amount of 20.000 to 50.000 MKD, and it shall be imposed a safety measure – prohibition of performing responsible duty for a period of three months to one year.

iii) consumer credit (Directive 87/102/EEC as amended by Directives 90/88/EEC and 98/7/EC)

The full transposition of Directive 87/102/EEC as amended by Directives 90/88/EEC and 98/7/EC in the national legislation will be finished by the end of 2006.

At the moment, part of the issues treated by Directive 87/102/EEC as amended by Directives 90/88/EEC and 98/7/EC are regulated with the Law on Obligations (“Official Gazette of RM” No. 18/01, 4/02 and 5/03) through:

- Article 12, which determines that in the process of establishing the obligation relations and implementing the rights and obligations resulting from such obligations, the entities are obliged (if when performing their business activities they are directly providing services to citizens) to define and perform their rights and obligations in such a manner, so that they are in compliance with the basic consumer rights defined by the Law on Obligations, by other laws, and by international agreements ratified by the Republic of Macedonia.
- Article 23, which defines the place and time of entering into contract.
- Articles 132 to 134 which regulate the assignment of contracts to third parties, and the rights pertaining to the user (in this case the consumers) from the assignee.
- Chapter XXXIX (Articles 1104 to 1107), which regulates the forms of contract of credit, its contents (amount, terms for awarding, using and returning the credit), and the conditions for termination of the contract and returning the credit ahead of time.

iv) package travel, package holidays and package tours (Directive 90/314/EEC)

Directive 90/314/EEC is fully implemented in the Law on Tourism (“Official Gazette of RM” No. 62/04) with the provisions of Articles 2, 16, 18, 20, 21, 22, and 23 which specifically determine the liability of travel agents when organising travel packages. At the same time, this Law stipulates liability and obligation on the part of the travel agency to conclude a contract with the user of the travel package, as well as an obligation to actually perform the travel package, and an obligation for the organiser of the travel to conclude an insurance policy with an appropriate insurance institution. The contracts for organised travel are regulated by the Law on Obligations (“Official Gazette of RM” No. 18/01, 4/02 and 5/03), Articles 915 to 935, and with the Mediatory Contract for Travelling, Articles 936-940 of the same Law.

v) unfair terms in consumer contracts (Directive 93/13/EEC)

Directive 93/13/EEC is fully implemented in the provisions of Articles 53 to 83 of the Consumer Protection Law (“Official Gazette of the RM” No. 38/04), see [23 Annex 01](#). Article 53 defines the term “unfair contractual provisions”, and then the specific cases of provisions that are considered unfair are mentioned in the following articles, finishing with the provisions stipulating that the ambiguous or incomprehensible contractual provisions shall be interpreted in favour of the consumer, and that the unfair contractual provisions shall be considered null and void.

According to Article 137 of the Consumer Protection Law, the legal entity shall be fined for infraction with the amount from 80.000 to 250.000 MKD if it imposes contractual provisions which are stated as unfair in Articles 54 -77 and 79 of this Law. In addition to the fine, the legal entity shall also be imposed a safety measure – prohibition of performing activity for a period from one to three years. The responsible person of the legal entity shall be fined for the infraction with an amount of 20.000 to 50.000 MKD, and it shall be imposed a safety measure – prohibition of performing responsible duty for a period of three months to one year.

vi) purchase of the right to use immovable properties on a timeshare basis (Directive 94/47/EC)

Directive 94/47/EEC is fully implemented through the provisions of Articles 108 to 120 of the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), which regulate the way of concluding the relevant contracts, the contents of the preliminary contract, as well as the contract, the possibility of registering the right to use immovable property in the public register, etc.

According to Article 138 of the Consumer Protection Law, a legal entity shall be fined for infraction with the amount from 80.000 to 240.000 MKD if it does not deliver the written notice in terms of Article 110 paragraphs 1 and 3 of the Law; if the content of the contracts do not include the provisions laid down in Article 111 of the Law; if it does not inform the consumer about modifications of any data stated in the prior notification (Article 112 paragraph 3); if, when calculating public services, does not act in accordance with Article 118 paragraph 2; if it does not provide for all consumers to connect and use of the utilities and public services network under non-discriminatory and in advance known and accepted conditions (Article 119 of the Law); if it does not maintain the standards and quality of services determined in a law or a regulation (Article 120 of this Law). In addition to the fine, the legal entity shall also be imposed a safety measure – prohibition of performing activity for a period from two to four years. The responsible person in the legal entity, if it does not comply with the aforementioned provisions, will be fined for the misdemeanour with an amount from 20.000 to 50.000 MKD.

vii) distance contracts (Directive 97/7/EC)

Directive 93/7/EC is fully implemented through the provisions of Articles 84 to 104 of the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#). The provisions of these Articles define the term "contracts concluded at distance" and "means of distant communication", to which these provisions apply, as well as the prohibition on conclusion of particular contracts by those means. The rights, periods, ways and consequences of contract termination, as well as the burden of proof, are also regulated.

viii) comparative advertising (Directive 97/55/EC amending Directive 84/450/EEC)

Directive 97/55/EC amending Directive 84/450/EEC relating to comparative advertising is fully implemented in the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), through the provisions of Article 24 paragraph 3, which determines what is considered comparative advertising, and Article 29, which determines the conditions under which comparative advertising is not permitted.

ix) indication of the prices of products offered to consumers (Directive 98/6/EC)

Directive 98/6/EC is fully implemented through the provisions of Article 8 of the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), where it is determined what is considered a retail price and its contents, the way of indication of the prices and the obligation for the traders to abide by the indicated retail prices. Also, the provisions of Article 10 paragraph 3 stipulate that in cases when products are wrapped in special paper or additional decorations, the price of those products and the wrapping service shall be indicated clearly and on a visible place.

x) injunctions for the protection of consumers' interests (Directive 98/27/EC)

The Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), authorises the State Market Inspectors to impose administrative measures (Articles 130 – 135), while Article 134

authorises them to decide on temporary confiscation of products, apart from imposing administrative measures for certain activities. At the same time, if there has been a violation, the state market inspectors have the obligation to request filing of misdemeanour charges for the activities stated in the penalty provisions of Articles 136 – 139.

However, the Law on Executive Procedure (“Official Gazette of RM” No. 53/97, 59/00 and 64/03) determines that the Courts impose provisional measures according to the provisions of Articles 263-275 of this Law. This Law also determines the possibility of temporary securing of monetary and non-monetary claims provided that the creditor proves there is a risk of obstructing or aggravating the accomplishment of the creditor’s claim if the proposed measure is not accepted.

The new Law on Execution and Securing, which is in parliamentary procedure (the former Law on Executive Procedure), will provide for an essential change of the enforcement procedure - it will be implemented out of Court.

In relation to the determination and the implementation of provisional measures for the purpose of securing monetary claims, any measure for achieving such a goal is permitted, and especially the following measures:

- Imposing a ban on the debtor to utilize movable objects, as well as to keep such objects;
- Imposing a ban on the debtor for alienation or encumbrance of his/her immovable property or related rights on immovable property registered in his/her name, with a notification of such a ban in a public register; or leasing them to a third party;
- Imposing a ban on the debtor to sell bonds or shares;
- Imposing a ban on a debtor’s debtor to pay them off an active debt, or to pass on objects; as well as a ban on the debtor to receive objects, to charge claims and to have them at their disposal; and
- To issue an injunction to the bearer of payment operations of the debtor or of a third party, upon a debtor’s order, to allow payments from debtors’ accounts in the amount of the sum a provisional measure was allowed for.

Provisional measures do not provide the right to lien. (Article 286)

If the creditor has made the claim probable, and if there is danger that the accomplishment of the claim could be obstructed or aggravated, the conditions for allowance of provisional measures for securing non-litigation claims are met.

Provisional measures could also be allowed if the creditor proves that the measure is necessary for prevention of use of force, or of establishment of a non-compensational damage. (Article 287)

The provisions of Article 285 paragraphs 2 and 3 of this Law are also implemented in relation to the provisional measures for securing non-monetary claims.

Any measure for achieving security of non-monetary claims is permitted, especially the following measures:

- Imposing a ban on alienation or encumbrance of movable objects to which the claim refers, as well as on keeping those objects;
- Imposing a ban on alienation or encumbrance of immovable property to which the claim refers, with a notification on the ban in a public register;
- Imposing a ban on the debtor to take actions that could damage the creditor, as well as a ban on making changes to the objects to which the claim refers.
- Imposing a ban on debtor’s debtor to deliver the objects to which the claim refers; and
- Paying off contributions for salary for workers during a dispute on the unlawfulness of a decision for termination of employment, if it is necessary for their support and the support of the persons that they are legally bound to support (Article 288).

xi) certain aspects of the sale of consumer goods and associated guarantees (Directive 1999/44/EC)

Directive 99/44/EEC is fully implemented through certain provisions of the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#). Article 21 determines the obligation of the trader, during the sale of products, to give and point out to the consumer the prescribed documents and the documents prepared by the producer for the purpose of easier and safe use of the product, i.e. declaration, warranty, technical manual, manual for assemblage, instructions for use, list of authorised services etc. Article 22 determines the obligation of the producer to ensure and to abide to the obligations from the warranty, the contents of the warranty, and that the documents should be written clearly and legibly, in Macedonian language and its Cyrillic alphabet, which does not exclude the possibility for additional use of other languages and signs easily understandable to the consumer. The provisions of Article 45 determine the conditions for exercising the consumer's rights, as well as the obligations of the trader or the producer to meet the consumer's requests, while the provisions of Article 46 refer to placing requests for eliminating defects of products discovered during the warranty period, or within the period for safe use of the product, determined by the producer. Article 48 determines that the defects discovered by the consumer should be eliminated by the trader within 20 days from the moment of submission of the request by the consumer or after receiving the decision of the competent supervisory body ordering the trader to eliminate the defects in a specified period. In case of requests for replacement of products with warranty periods, the warranty for the new product shall be running from the day when the product replacing the defective product was delivered to the consumer.

xii) distance marketing of consumer financial services (Directive 2002/65/EC amending Directives 90/619/EEC, 97/7/EC and 98/27/EC)

Directive 2002/65/EC amending Directives 90/619/EEC, 97/7/EC and 98/27/EC has not been transposed in the national legislation.

The transposition of the above Directives will be finalised by the end of 2007, while the practical application of distance marketing of financial services will be implemented successively, according to the dynamics of liberalisation of capital transfers stipulated by the Law on Foreign Exchange Operations ("Official Gazette of RM" No. 34/01, 49/01, 103/01, 54/02) and according to the degree of liberalisation of the market of certain financial services.

xiii) codes of practice for the protection of consumers in respect of contracts negotiated at a distance (distance selling) (Commission Recommendation 92/295/EEC)

The codes of practice for the protection of consumers in respect of contracts concluded at a distance are implemented in the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), on the basis of Directive 97/7/EC. The Commission Recommendation 92/295/EEC has not been implemented specifically.

xiv) principles applicable to the bodies responsible for out-of-court settlement of consumer disputes (Commission Recommendation 98/257/EC)

In comparison with the European standards and practice in the European countries, there has been no developed system for alternative dispute resolution.

There is a plan for adoption a Law on Mediation, which will introduce the institute of mediation and the out-of-court dispute resolution, regulating cases and different forms of mediation and reconciliation and arbitrary dispute resolution, as well as the legal consequences of the acts and decisions brought during such out-of-court proceedings.

A programme for selection and education of mediators will be prepared after the adoption of the Law on Mediation, and the procedures for conducting exams for mediators and the Ethical Code for Mediators will be prepared, too.

This Law is expected to be adopted in 3 years time.

xv) principles for out-of-court bodies involved in the consensual resolution of consumer disputes (Commission Recommendation 2001/310/EC)

The answer of this question is contained in the answer to the previous one.

xvi) pre-contractual information to be given to consumers by lenders offering home loans (Commission Recommendation 2001/193/EC)

The Commission Recommendation 2001/193/EC has not been transposed in the national legislation. This is expected to be accomplished by the end of the year 2006.

c) Other areas

i) television broadcasting activities (Directive 89/552/EEC amended by Directive 97/36/EC)

The Broadcasting Law ("Official Gazette of RM" No. 20/97, 70/03), see [20 Annex 01](#), regulates the rights relating to the protection of the interests of consumers as television audience in several segments, and specifically regarding:

- Introduction of appropriate standards and rules on advertising and sponsorship;
- Rules on the protection of the physical, mental and moral development of juveniles;

Advertising is regulated by the provisions of Articles 48 to 57 of this Law. These provisions determine the principles of advertising, the duration of advertisements and teleshopping, the ways of inserting the advertisements in the broadcast, the prohibition for advertising certain products (drugs, tobacco, alcohol, and prescription medicine). There is a special provision regulating that advertisements should not manipulate the general audience and should be not adverse to the interests of consumers, or users of services, intended for protection of the consumers and the users of services. There is also a provision stipulating that advertisements for children, or advertisements in which children participate, must not contain messages that could damage their interests or have negative influence on children's sensitivity and age.

The broadcasting of teleshopping is restricted to one hour per daily programme, and it refers only to the commercial broadcasting enterprises. Public broadcasting enterprises cannot provide such services (Article 51, paragraphs 3 and 4).

Sponsorship is regulated by the provisions of Articles 58 to 61. They stipulate that the sponsor must be clearly identified, that they cannot influence the contents of the sponsored programmes, and that the sponsored programmes should not encourage sales, purchase or lease of sponsor's products. News and other informative programmes, as well as programmes of political or religious nature cannot be sponsored.

The protection of juveniles is regulated by Article 35 of the Law, which stipulates that programmes must not include indecent features, especially pornography and violence, neither programs which might have a negative impact on physical, spiritual or moral growth of children and youth. Films and other programmes that might have such an impact can be broadcast only between 24:00 and 06:00 hours.

With regard to the ratification of the Cross-border TV Convention by the Parliament of the Republic of Macedonia, there have been reserve in relation to Article 15, paragraph 2 of the Convention, and the Republic of Macedonia has retained the right to restrict the retransmission of television programmes on its territory if they contain advertisements for alcoholic beverages, since the existing Broadcasting Law prohibits all advertising of alcoholic beverages.

The implementation of Directive 89/552/EEC amended by Directive 97/36/EC is explained in details in the answer to question B. - Legal framework, c) - other areas, section 2.

A detailed explanation of the provisions of the Broadcasting Law is given in Chapter 20 – Culture and Audiovisual Policy, in the answer to question I. Audiovisual Policy, section 1, (for more details see [20 I 1](#)).

ii) electronic commerce (Directive 2000/31/EC)

The Trade Law (“Official Gazette of RM” No. 16/04) provides for the wholesale and retail commerce through means of communication. Article 64, paragraph 4 of the Law on Obligations (“Official Gazette of RM” No. 18/01, 4/02 and 5/03) allows for contracts to be concluded in writing, or through teleprinter, fax, computer, or any other means which allows for the content and the giver of the statement to be correctly determined. Articles 84–104 of the Consumer Protection Law (“Official Gazette of RM” No. 38/04), see [23 Annex 01](#), provide for contracts concluded using one or more means of distant communication (a telephone with or without human intervention, radio, videophone, videotext, fax, television, electronic mail, etc.)

There is no legislation on electronic commerce in the Republic of Macedonia and the Directive 2000/31/EC has not been transposed in the national legislation.

iii) medicinal products for human use (Directive 2001/83/EC)

The area of drugs and medicinal products for human use is regulated by the Law on Drugs, Additional Medical Products and Medical Devices (“Official Gazette of RM” No. 21/98).

The following secondary legislation has been passed on the basis of this Law:

- Rulebook on Conditions Relating to Facilities, Equipment and Staff that are Mandatory for Legal Entities Registered for Wholesale of Drugs, Additional Medical Products, and Medical Devices which are Use in Human Medicine (“Official Gazette of RM” No. 64/02);
- Rulebook on the Manner of Prescription and Selling Medicine and Medical Devices on Prescription (“Official Gazette of RM” No. 17/02);
- Rulebook on Organising and Monitoring the Manner of Reporting and Data Relating to the Confirmed Undesirable Side Effects of Medicinal Products Use (“Official Gazette of SFRJ” No. 57/87);
- Rulebook on Clinical Drug Testing (“Official Gazette of SFRJ” No. 2/89);
- Instructions on Methods of Laboratory Testing of Drugs Before Putting into Circulation (“Official Gazette of SFRJ” No. 34/89);
- Ordinance on Drugs Subject to Special Inspection before Putting into Circulation (“Official Gazette of SFRJ” No. 22/88);
- Decision on Drug Classification (“Official Gazette of SFRJ” No. 47/85, 73/85 and “Official Gazette of SRM” No. 54/90);
- Instruction for Conducting the Procedure for Issuing Approval for Putting into Circulation of Final Drugs (“Official Gazette of RM” No. 49/04);
- Instruction on Research of the Biological Availability and Bioequivalence of Medications. (“Official Gazette of RM” No. 68/04);

The implementation of Directive 2001/83/EC is explained in more details in the answer of question B. - Legal framework, c) - other areas, section 2.

2. Please indicate for each of the above listed pieces of legislation the basic features of the respective legislation, including enforcement mechanisms, and plans for reform. For implementing regulations, please specify which regulations have already been adopted and give an indicative timetable for those that still need to be adopted.

The answer to question B, 1, i, provides definitions for the terms safe product, dangerous product, as well as the obligation for providing information given by the trader concerning the product and putting safe products into circulation, pursuant to Directive 92/59/EEC and revised Directive 2001/95/EEC on General Product Safety, and in particular Article 8 thereof, whereas new Law on General Product Safety is foreseen to be enacted in the course of 2005.

The existing Broadcasting Law ("Official Gazette of the RM" No 20/97, 70/03) implements significant part of the provisions of the Directive "Television Without Frontiers". The Ministry of Transport and Communications is currently preparing the new Broadcasting Law which will completely implement the Directive 89/552/EEC amended by Directive 97/36/EC. Namely, new provisions are introduced in the part relating to television programmes which regulate TV advertising, sponsorship and teleshopping, protection of the interests of consumers, protection of juveniles from harmful content etc. Besides the existing restrictions as regards the forms of television advertising for narcotics, cigarettes and other tobacco products, as well as for medicinal products and medicinal treatment available only by prescription, the new Law will prohibit television advertising for weapons and companies that sell weapons, as well as for telephone services with pornographic content with special tariffs (in the period from 06:00 to 24:00). Taking into account that advertising for alcoholic beverages is being liberalised, the new Law stipulates new rules concerning the advertising for alcohol, completely harmonized with the Directive "Television Without Frontiers". As regards the advertising for medicinal products and medicinal treatment available without prescription, new principles are introduced according to which this advertising will be clearly recognisable, true, subject to inspection and shall protect individuals from adverse effects on their health. The new Broadcasting Law is expected to be enacted in 2005.

The Law on Drugs, Additional Medical Products and Medical Devices ("Official Gazette of the RM" No 21/98) regulates the conditions relating to putting into circulation, production and trade, inspection of quality, safety and efficiency, as well as supervision over production, putting into circulation, trade and quality of drugs, Additional medical products and medical devices, as activities of public interest.

The drugs, additional medical products and medical devices are placed on the market after obtaining relevant approval issued by duly authorised body of the Administration upon a proposal from the Committee on Drugs, Committee on Additional Medical Products and Committee on Medical Devices. The members of these Committees are appointed by the Minister of Health and Minister of Agriculture, Forestry and Water Management, from among the distinguished medical, dental, pharmaceutical, veterinary and other experts and scientists.

This Law regulates the conditions and methods of issuing approvals for production of drugs, as well as placing them on the market.

The Law prohibits drugs, additional medical products or medical devices placing on the market, if harmful for people, animals and environment. At the same time, it is prohibited to place on the market a drug or medical device that contains or represents a genetically modified organism such as live vaccines, viruses, modified body cells for therapeutic use for genetic diseases, gene carriers and other such products, unless they have been duly examined during test and development phases as regards their adverse impact on eco-systems.

In addition to the above, the Law regulates the conditions for terminating the approval for placing drugs, additional medical products and medical devices on the market before approval validity has expired.

This part, besides of the request for placing products on market, also regulates the following issues: procedure for issuing approvals for placing on markets; approval for placing on market; holder of

approval for placing on market; packaging and labelling; quality, safety and efficiency testing, clinical testing; approval for placing the first produced series of drugs which are subject to special control, as well as for each series of imported drugs, additional drugs and medical accessories; monitoring the safety and efficiency after placing products on market and informing and advertising for drugs and methods of drug prescription.

The conditions for production, wholesale and retail sale, pricing methods, supervision and penalties are regulated with special chapter of the Law.

Special chapters of the Law on Drugs, Additional Medical Products and Medical Devices regulate the conditions concerning the space, equipment and personnel, as well as obtaining licences for production, wholesale (distribution) and retail sale (pharmacies), pursuant to the principles of Good Production Practice, Good Laboratory Practice, Good Distribution Practice and Good Pharmaceutical Practice.

Furthermore, the issue of pricing is covered by special Chapter of the Law, as well as the methods of pricing relating to drugs, which is in connection with the List of Essential Drugs.

Future plans:

- The Law on Drugs, Additional Medical Products and Medical Devices is foreseen to be amended during 2005, pursuant to Directive 2001/83;
- Articles 87-99 of the Law on Drugs, Additional Medical Products and Medical Devices, are foreseen to be amended pursuant to Directives 1991/356; 2003/95; 78/25; 81/464 and Regulation 803/2003;
- Articles 77-79 of the Law on Drugs, Additional Medical Products and Medical Devices, are foreseen to be amended pursuant to Regulation 95/504;
- Articles 115-117 of the Law on Drugs, Additional Medical Products and Medical Devices, are foreseen to be amended pursuant to Directive 89/105;
- Taking the Directive 2002/98 into consideration, secondary legislation relating to proprietary medicinal products derived from human blood and human plasma is foreseen to be enacted;
- Taking the Directive 1998/079 into consideration, secondary legislation or amendments to Articles of the Law on Drugs, Additional Medical Products and Medical Devices are foreseen to be enacted;

The secondary legislation deriving from the Law on Drugs, Additional Medical Products and Medical Devices, shall be enacted within a period of one (1) year as of the date of entering into force of the amendments to this Law.

A Rulebook on Data for Drug Manuals is to be adopted pursuant to Directive 2001/83.

Part B – Legal Framework, item b), points iii, xii, xiv, xv, xvi stipulate the terms for harmonization with Directives and Commission Recommendations, (fore more details see [23 B 1](#)).

3. Specify which authorities are competent for drafting the relevant legislation and how legislation is passed (primarily through parliamentary procedure or ministerial orders or decrees).

The ways and procedures for adoption of laws are regulated by the Constitution of the Republic of Macedonia, while the work of the Assembly of Republic of Macedonia in this domain is regulated by the Rules of Procedure of the Assembly of Republic of Macedonia ("Official Gazette of RM" No. 60/02).

The Constitution of the Republic of Macedonia, *inter alia*, stipulates that: "The right to propose adoption of a law is given to every Representative of the Assembly, to the Government of the Republic and to a group of at least 10,000 voters. The initiative for adopting a law may be granted to the authorised instances by any citizen, group of citizens, institutions or associations."

Pursuant to Article 106 of the Rules of Procedure of the Government of the Republic of Macedonia, the Government, in cases where it appears as an authorised instance, submits to the Assembly proposals for adoption of law, draft law, proposal of law and other regulation that is adopted by the Assembly of the Republic of Macedonia, in a form and according to the procedures determined by the Rules of Procedure of the Assembly of the Republic of Macedonia.

The legislation in the Republic of Macedonia is generally adopted in a regular procedure of two readings, namely a Proposal to Adopt a Law and Draft Law. Bu exception, the Assembly may decide a law to be also examined as a Preliminary Draft-Law. In addition to the standard procedure, there is also a shortened or an urgent procedure for adopting legislation, which is also provided for by the Rules of Procedures of the Assembly of the Republic of Macedonia.

The Assembly of Republic of Macedonia, during the consideration of the Proposal to Adopt a Law, may decide that the drafter should submit a Preliminary Draft-Law, instead of a Draft Law.

The drafter of the law, pursuant to the Rules of Procedure of the Assembly of the Republic of Macedonia, may submit to the Assembly a Proposal to Adopt a Law with a Draft Law, if the law in question is not complicated and voluminous.

Also, according to the Rules of Procedures of the Assembly of Republic of Macedonia, there is a possibility for adopting legislation by an urgent procedure.

In principle, all legislation is discussed by the relevant Commissions of the Assembly of the Republic of Macedonia and the Legislative and Legal Commission of the Assembly.

During the discussions on certain Draft Law which are of public interest, the Assembly may decide to conduct a public discussion about the Draft Law. The Draft Law which is put to public discussion is published in the daily press determined by the Assembly, with a call for submitting opinions and suggestions within a certain period, on the basis of which the drafter of the Law submits a Draft Law.

The Assembly of the Republic of Macedonia adopts legislation by a majority vote of the Representatives attending, but no less than one-third of the total number of Representatives, unless, by the Constitution, qualified majority is requested.

For laws directly concerning culture, usage of languages, education, personal documents and the usage of symbols, the Assembly decides with a majority vote of the Representatives attending, including a majority vote of the Representatives of the non-majority communities in the Republic of Macedonia attending.

The procedure for amending the laws is carried out by submitting amendments, with a procedure provided by the Rules of Procedures of the Assembly of the Republic of Macedonia.

The laws proposed by the Government of the Republic of Macedonia or the authorised instances are adopted by the Assembly of the Republic of Macedonia.

When the Assembly of the Republic of Macedonia asks the Government of the Republic of Macedonia for an opinion on a Proposal to Adopt a Law, Draft Law or other regulation that has not been proposed by the Government itself, the Government forms an opinion before the consideration of the proposed legislation in the Assembly of the Republic of Macedonia. The Government submits its opinion within 15 days from the day of receipt of the proposal, and by exception it may authorise a representative to deliver the Government opinion on an Assembly session.

All legislation in the Republic of Macedonia is adopted by the Assembly of the Republic of Macedonia, through a parliamentary procedure.

C. SPECIFIC QUESTIONS ON PRODUCT SAFETY AND MARKET SURVEILLANCE

1. Please comment on the important aspects of the infrastructure for general product safety as described below by referring to your national system for market surveillance:
- a) market surveillance/enforcement authorities with defined responsibilities and sufficient powers and resources to monitor the compliance of products with the directive and to react to complaints;
 - b) rapid and well functioning legal system for taking measures in cases of breaches of the legislation and for appropriate means of redress in respect of measures taken;
 - c) systematic approaches (surveillance programs, follow up of scientific and technical knowledge, review and revision of the functioning of the activities) to ensure the effectiveness of market surveillance;
 - d) customs control for checking conformity of products imported from third countries;
 - e) system for co-operation between market/surveillance bodies with responsibilities in relation to enforcement of different types of consumer products as well as with customs (regulation 339/93);
 - f) defined methodology for risk-assessment and access to technical expertise and competent and independent testing facilities for checking conformity of products;
 - g) access to information on product dangers to the public respecting professional secrecy and restrictions required for monitoring and investigation activities;
 - h) system for co-operation and information with producers and distributors and consumer associations with regard to providing and receiving information and exchange of experiences;
 - i) system for providing rapid information to consumers and businesses through the media;
 - j) system for ensuring administrative co-operation with other countries;
 - k) co-operation with the national standardisation body with regard to the use of standards under the directive and to ensure co-operation of all parties concerned (including consumers) in the development of standards related to consumer products;
 - l) systems for collection of product related injury data (such as the EU EHLASS programme);
 - m) number of controls carried out and the results, the reasons for the controls (own initiative/complaints), type of products controlled, the geographical coverage of the controls, the way the controls have been carried out (ocular examination/testing).

a)

The State Sanitary and Health Inspectorate, State Agriculture Inspectorate, State Environment Inspectorate, Veterinary Administration – Veterinary Directorate, as well as the State Market Inspectorate, pursuant to regulations defining their authority as described in question A – General issues, under 3, b) and c), are responsible for market surveillance and enforcement of laws relating to general product safety, (for more details see [23 A 3](#)).

b)

If during market surveillance, the responsible inspection bodies determine breach of legislation or law non-enforcement by legal entities and natural persons, they are obliged to issue a Decision by means of which an administrative measure, prescribed by law, shall be undertaken. The inspection services are authorised with the Decision to order for removal of the determined deficiencies in case there are no conditions for market circulation, to prohibit placing certain products on market due to inappropriate quality or expired product date of use, to obliterate defective products, to remove agricultural products from sale if they cause adverse effects on the health of people, plants and cattle, to prohibit fallacious advertising, to order replacement or reimbursement of purchased product etc.

Pursuant to the Law, a Party has the right to an appeal against the Decision of the responsible inspector, within a period stipulated in the Decision.

The appeals against the decisions of the responsible inspection bodies do not postpone their enforcement.

Along with the Decision, the responsible inspectors are obliged to request for misdemeanour procedure, or to file criminal charges with the responsible court.

c)

The State Inspection Bodies carry out the supervision according to adopted programmes (annual programmes, semi-annual and quarterly plans).

The Law on Organisation and Operation of the State Administrative Bodies ("Official Gazette of the RM" No 58/00 and 44/02), as well as acts relating to public inspection bodies, provide for education of inspection bodies through different surveillance programmes, participation at scientific and educational seminars and meetings aimed at introducing the bodies with their work.

d)

Pursuant to the provisions of the Trade Law ("Official Gazette of the RM" No. 16/04), goods can be imported only if fulfilling prescribed conditions as regards demonstrating evidence, issued by legally authorised bodies, before the customs administration units for fulfilling the special conditions. The customs administration bodies do not control conformity of products imported from third countries.

Responsible non-customs institutions (State Market Inspectorate, State Sanitary and Health Inspectorate, State Agriculture Inspectorate, Veterinary Administration – Veterinary Directorate, State Environment Inspectorate etc.) provide evidence for the conformity of the products and carry out the controls of products imported from third countries.

The non-customs institutions carry out the necessary controls and check conformity of products while performing customs supervision of goods, and before customs procedures are initiated by customs administration bodies.

After obtaining the necessary evidence, the evidence is enclosed and retained in the customs declaration, and appropriate customs procedures can be initiated. In case the imported goods lack the evidence as required, the customs body shall not accept the customs declaration and shall not allow for customs clearance of goods.

e)

The public administration inspection bodies are obliged to mutually co-operate, and co-operate with other public administration bodies, whilst performing inspection activities of common interest pursuant to Article 53 of the Law on Organisation and Work of the State Administration Bodies.

If irregularities are established during inspection supervision, inspection bodies are obliged to inform the responsible body i.e. inspection service which is to undertake appropriate measures within the frames of its authorisations.

The co-operation with customs administration understands that product which is subject to customs control cannot be cleared and placed on the market of the Republic of Macedonia until evidence that imported products are in accordance with prescribed legal conditions is presented by the State Market Inspectorate, State Sanitary and Health Inspectorate, State Agriculture Inspectorate, State Environment Inspectorate and Veterinary Administration – Veterinary Directorate.

The responsible inspection bodies co-operate with non-customs institutions and officials of customs bodies on a regular operational basis as regards enforcement of activities and controls before and after import clearance of goods.

Evidence verifying that goods are in accordance with the prescribed legal conditions, issued by different non-customs institutions, are enclosed in the customs declaration through customs declarer in writing, which is subject to customs bodies control upon request.

In the Republic of Macedonia, a National Strategy for Integrated Border Management has been prepared, and the Law on Integrated Border Management Cooperation, supported by the European Agency for Reconstruction, is currently in enactment procedure, which shall prescribe the methods of joint co-operation in the field of border management. Agreements are foreseen to be concluded between administrative bodies involved in border management, in order to define competencies of parties, work procedures, mutual assistance modality, information and data exchange, access to central data base, public information, joint training and other activities that will improve service operations.

This shall also relate to the issue of import and export of goods, aimed at consumers protection from unsafe goods.

f)

Legal regulations provide an opportunity for checking of products in accredited institutions for product certification and testing. The methodology of work (taking samples, procedures with samples, notifying owners of goods, notifying concerned parties etc.) is regulated by special laws and secondary legislation.

Pursuant to the Law on Prescribing Technical Requirements for Products and Conformity Assessment (Official Gazette of the RM No. 55/02), certain types of products can be tested based on regulations in force.

For example, according to the Law on Technical Inspection ("Official Gazette of the RM" No. 48/99), the State Inspector for Steam Boilers and Pressurised Plants, controls the technical documentation and technical functionality during import of mobile pressurised tanks. After import of pressurised tanks – for liquid petroleum gas, installed in motor vehicles, the State Inspector controls the tanks by using methods determining pressure endurance in Bars. Afterwards, certain parts of the pulverised tanks are tested in authorised laboratories for testing material quality. The material quality is tested according to the producer's documentation, and certificate of functionality is issued for each tank.

g)

Pursuant to the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), dangerous products shall be considered the products which have the form, scent, colour, appearance, packaging, labelling, volume or size and as such, it is possible that the consumers, especially children, misplace them for foodstuffs and place them in the mouth, suck or swallow them, which may be dangerous and may cause, for instance, suffocation, poisoning, perforation or obstruction of the digestive tract.

At the same time, according to this Law, the producers, traders and distributors are obliged to provide information about the risks arising from certain products. In addition, pursuant to the Law, the producers and distributors, in cases when they know or presume that the products placed on the market are risky for the consumers, are obliged to undertake measures to withdraw the products from the market.

The responsible inspection bodies, within the frames of their activities, shall determine which products are dangerous and shall initiate activities for determining their quality and risk for

consumers, and afterwards undertake measures and co-operate with producers and consumers so as to remove the risks that could arise from certain products.

The Law on Free Access to Information, currently in Parliamentary procedure, which will contribute towards determining the type of information that is not relevant for citizens, and it will also foresee an obligation for the public administration bodies as regards determining type and level of information relevant for citizens.

h)

Pursuant to Article 128 of the Consumer Protection Law ("Official Gazette of the RM" No 38/04), the associations of consumers are entitled to inform the competent inspection body when they learn about defective products and services or dangerous products and services. In addition, the associations are entitled to give information to the consumers regarding their rights and the events on the market.

Pursuant to the Law on Market Inspection ("Official Gazette of the RM" No 35/97, 23/99, 07/02 and 20/02), the inspector is obliged to initiate procedures regarding the complaints of consumers and their associations relating to breach of regulations which are in the competence of the market inspection. The inspector is obliged to inform the consumers who have lodged complaints on the determined situation and undertaken measures.

The Macedonia Consumers Organisation actively co-operates with all inspection bodies competent in the consumer protection domain. Consumer complaints addressed to the Counselling Bureaus of the Macedonia Consumers Organisation are daily submitted to the competent inspection bodies, which undertake measures pursuant to legal regulation and afterwards inform the Organisation.

The co-operation with the Macedonia Consumers Organisation is especially important in terms of preventive protection through information systems – "Infoteques" for consumer rights, giving information to consumers about their rights and obligations, as well as information on certain events on the market.

There is mutual co-operation in terms of exchange of experience through joint meetings and educational seminars.

i)

The competent governmental institutions and inspection bodies are authorised to inform the consumers about dangers and risks of certain products, by means of media, press-conferences and other means on information.

The Macedonia Consumers Organisation communicates and co-operates with all printed and electronic media in the Republic of Macedonia, and makes efforts so as to introduce a higher level of transparency within its activities.

j)

The administrative co-operation with other countries in the field of consumer protection and safety on market is regulated by bilateral and multilateral international treaties and agreements. Generally, the Ministry of Foreign Affairs is responsible for administrative co-operation with other countries.

k)

Pursuant to the existing Law on Standardisation ("Official Gazette of the RM" No. 54/02) the standards are applied on a voluntary basis, not obligatory. However, in order to prepare standards upon request of concerned parties, it is necessary to establish a special technical committee of the concerned parties, according to the Statute of the Standardisation Institute of the Republic of Macedonia, which may also include consumers depending on their interest or depending on how much the standard refers to the product standard, which is of interest for the consumers. The

Standardisation Institute co-operates with international standardisation organisations, such as: CEN (European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization), IEC (International Electrotechnical Commission) and ISO (International Organization for Standardization).

l)

The Republic of Macedonia, at this moment does not have developed system for collection of product related injury data (such as the EU EHLASS programme).

m)

The State Sanitary and Health Inspectorate officially supervises all regions in the Republic of Macedonia on a regular basis (The State Sanitary and Health Inspectorate which consists of 17 regional branches and 1 Border Surveillance Unit which has jurisdiction over the country's border crossings.). Supervision is carried out in case there are grounds for suspicion or if citizens have lodged complaints. Supervision is also carried out upon request of producers and traders if it is required to independently obliterate food due to defects or expired date of use, in which case no administrative sanctions are undertaken.

The State Sanitary and Health Inspectorate, in 2003, on the entire territory of the Republic, has performed 25.729 controls, out of which 6.127 controls of tourist-catering facilities, 8.501 controls of facilities for retail sale of food, 2.840 controls of facilities for manufacture food production, 687 controls of food wholesale facilities, 896 controls of facilities for industrial food production, 1.014 controls of social and educational facilities and camps for children, 71 control of public health institutions, 2.118 controls of private health institutions, 277 controls of city water-supplying facilities, 523 controls of local water-supplying systems, 26 controls of facilities releasing harmful substances in air, 811 controls of facilities for hygienic services, 125 controls of utilities and 1.004 controls of other facilities that were not mentioned previously.

Regarding the performed inspection supervisions, 8.817 Decisions in administrative procedure were adopted in order to remove the established defects, as well as Decisions for temporary prohibition for use of facilities.

State Sanitary and Health Inspectorate – Border Supervision Unit, in 2003, carried out health control of imported goods at customs terminals relating to a total of 21.020 requests submitted from importers. After completing the organoleptic control, five (5) decisions prohibiting the import of goods were adopted. 24.620 samples were tested in laboratories in connection with which 3 decisions were adopted due to microbiological contamination, and 28 decisions were adopted for the same products due to chemical incorrectness. Because there was no possibility of returning goods to the export-country, 14 decisions were adopted for obliteration of goods.

The samples are taken only by state sanitary and health inspectors, and the technical support covering hygienic sampling and transport is carried out with assistance of teams from regional institutes. The samples are tested in authorised laboratories – ten (10) regional health protection institutions, the National Health Protection Institute and the Faculty of Veterinary Medicine. The procedure, control and administrative measures to be undertaken shall depend on the results. The defective products may be obliterated, converted or processed, according to an adopted decision. In certain cases, the state sanitary and health inspectors may immediately obliterate organoleptically modified food, if there is immediate risk on the health of people.

Bureau of Medicines – The Inspection Supervision Unit, during 2003, performed 96 examinations in private health institutions – pharmacies.

Pursuant to the Law on Drugs, Additional Medical Products and Medical Devices (“Official Gazette of the RM” No. 21/98), the following controls were carried out in the field of retail sale of drugs, additional medical products and medical devices (pharmacies):

- Approval for performing activity, and premises and equipment inspection
- Examination of documentation for the employees, inclusive of sanitary record books

- Examination of the correctness of drugs, records on drugs issued on prescription, efficient narcotics record keeping

Pursuant to these provisions of the Law on Drugs, Additional Medical Products and Medical Devices, minutes were prepared concerning the current situation, and regarding the administrative measures, 12 decisions were adopted for closing pharmacies, and no misdemeanour charges were filed.

There were 57 inspection controls of legal entities active in the wholesale of drugs, additional medical products and medical devices so as to harmonise their activities with the new Rulebook on Conditions Relating to Premises, Equipment and Personnel for Legal Entities Active in the Wholesale of Drugs, Additional Medical Products and Medical Devices ("Official Gazette of the RM" No. 06/02).

All inspected wholesale pharmacies were harmonised with the Rulebook.

During 2003, the producers of drugs, additional medicines and medical instruments in the Republic of Macedonia were inspected, by the Inspectorates indicated below.

Minutes were prepared about the established deficiencies and irregularities concerning the premises, equipment and personnel. The harmonisation of production capacities for drugs is currently ongoing, as well as the adjustment with the standards of Good Production Practice and Good Laboratory Practice, prescribed with the Law on Drugs, Additional Medical Products and Medical Devices.

The State Market Inspectorate controls the food and non-food products on the national market, and also controls the agricultural imported food products.

During 2003, a total of 25.917 controls were carried out at the national market. As regards the established defects, 4101 administrative procedure decisions were adopted, 9.266 requests for filing misdemeanour charges, and mandatory fines in an amount of 909.000 Denars. Furthermore, 942 complaints of citizens were submitted.

Quality control of imported agricultural food products is carried out at the customs terminals. In 2003, 17.592 requests were submitted.

Product control is executed with organoleptic examination, and by taking samples, which are afterwards submitted to authorised institutions for chemical analysis. Certificates for 5.974 requests were issued based on the performed organoleptic examination, and based on the samples and analysis – certificates for 11.606 requests were issued. In addition, 39 decisions were adopted for rejecting the request for issuing the certificate of quality.

The State Market Inspectorate supervises the entire territory of the Republic of Macedonia through its organisation units.

The inspector may take samples and send them for analysis to authorised professional institutions for quality control. The procedures and measures to be undertaken depend on the results. In certain cases, for certain products, the inspector is authorised by law to carry out organoleptic control.

The State Veterinary Inspection, in 2003, has carried out 13.360 official controls of animal origin items out of which: 7.964 during import, 1.023 during export and 4.373 during transit. During controls and inspections in the production and trade process, the following products were confiscated as hygienically unsafe: 54.091 kg meat in internal trade, 2.513 kg imported and 25.541 kg exported; 24.814 kg meat products in internal trade, 17.655 kg dairy products in internal trade, and 2.785 kg fish and fish products in internal trade.

Furthermore, controls were carried out concerning trade in other types of products, raw materials and animal origin residues, as well as fodder such as: leather, wool, intestines, fat, fish meal, etc.)

The veterinary-sanitary control is carried out on regular basis according to prepared annual programme, on daily basis if there is initiative of an individual, and in case there are complaints concerning the production process in internal and foreign trade in items of animal origin. The control includes several procedures such as: examination of supporting documentation, item identity, production facilities, production and storing equipment, means of transportation, organoleptic

examination of products and taking samples for testing in authorised laboratories concerning the health related correctness and harmful residues. Inspections and controls were carried out on the entire territory of the state as regards internal trade, and at border points as regards foreign trade.

The State Agricultural Inspectors, for 2003, have carried out on the territory of the Republic of Macedonia 4.007 controls, prepared 3.698 minutes and adopted 535 decisions for removing defects of products and termination of production, as well as 18.087 controls at border crossings of imported products of vegetable origin and 26.475 controls of products intended for export.

The controls were official and upon complaints of consumers.

The State Agricultural Inspectorate, officially and upon complaints of consumers, has carried out controls of 8.037 tonnes of different types of seeds, out of which 77.480 kg of different types of seeds were temporarily confiscated and removed from the market. 1.365.467 items of plant material (fruit and vine) were inspected, out of which 67.707 items were temporarily confiscated and removed from the market, and a part was destroyed. 8.146 tonnes of fertilizers were inspected and 1.039 tonnes were removed from the market. 2.509 tonnes of fodder were inspected, and 112 tonnes were removed from the market pursuant to a decision of the inspector.

In order to precisely determine the quality of confiscated seed, fertilizers, fodder and wine, inspectors gave 184 samples to be tested in laboratories. According to the results, 6 samples were defective.

Operational activities were carried out by the agricultural inspection through controls and supervisions in 2.868 enterprises, 123 associations, 959 natural persons.

The State Environment Inspectorate submitted 66 requests for misdemeanour charges and two (2) for criminal charges in the period 2002 – 2004. To date, 23 requests for misdemeanour charges were solved, 4 requests were rejected as obsolete and the remaining are in ongoing court procedure.

2. Please give some indication of the level of activities in the field of market surveillance by providing statistics, as available, referring to some of the following examples:

- a) number of complaints received, from whom and actions undertaken;
- b) number and types of measures taken by market surveillance authorities;
- c) number and types of measures taken by customs authorities;
- d) number and types of product safety cases dealt with by the courts, average time-frame for a decision and average time for enforcement;
- e) number and type of rapid-alert measures notified to and from the central point and documentation on follow-up to such notifications;
- f) activities undertaken (meetings, information documents etc.) for ensuring co-ordination between authorities and interaction with economic operators and consumer organisations;
- g) information activities directed to the public;
- h) routines and meetings between product safety authorities and customs to ensure co-ordination of the customs control;
- i) details of systems for ensuring a systematic approach to control activities;
- j) statistics on injuries related to products;
- k) systems established to ensure consumer participation in relevant standardisation work;
- l) statistics relating to sales figures of consumer products, origin of the products etc.

a)

b)

The **State Market Inspectorate** received 942 complaints regarding the protection of consumer rights by citizens in 2003. The complaints were mainly filed by natural persons. The State Market Inspectors took immediate actions upon the complaints, during which they correctly established the factual situation and undertook administrative measures prescribed by law. Due to the actions taken by the inspectors of the State Market Inspectorate, all of the justified consumer complaints were

resolved positively. 942 supervisions were made, and 872 decisions on administrative measures were reached, ordering traders to act in accordance with the law, and the consumers' requests were satisfied.

In the area of consumer protection, a total of 25,917 supervisions were made upon complaints and ex officio, resulting in 9,266 misdemeanour procedures; 6 filed criminal charges; 4,101 decisions on administrative procedures; temporarily seized products turned over to the courts with the total value of 13.333.675 MKD; and products put out of circulation because of expired validity or lack of quality with the total value of 5.372.762 MKD.

The **State Sanitary and Health Inspectorate** acts immediately upon every written or oral complaint filed by natural persons or legal entities, as well as by consumer associations regarding the sanitary validity of products. Complaints generally regard food products.

Because of unsafe imported products and disregard of decisions brought by the State Sanitary and Health Inspectors, 12 charges for misdemeanours were filed before the competent courts in 2003. 128 charges for initiating misdemeanour procedures were filed for domestic products because of disregard of inspectors' decisions.

504 decisions prohibiting the use of objects until defects' removal were brought because of severe sanitary and hygienic norms violations.

The **State Agricultural Inspectorate** filed 782 charges for misdemeanour procedures in 2003, from which 88 charges were filed for misdemeanours committed by legal entities, while the rest of 694 charges, or 88.75%, by natural persons.

From the 782 filed charges for misdemeanour procedures, 90 charges, or 11.50%, were resolved, while 63 offenders were fined.

From the charges filed in 2002 and 2003, 339 were resolved in 2003, while the offenders were fined with a total amount of 1.070.620 MKD.

The **Veterinary Directorate** made a total of 13.360 controls of shipments of animal origin at the border crossings in 2003, pursuant to the Law on Veterinary Health ("Official Gazette of the RM No." 28/98), from which 7.964 controls of shipments for import, 1.023 controls of shipments for export, and 4.373 controls of shipments for transfer.

In 2003, 1.543 minutes on prevention and eradication of contagious diseases were prepared, and 506 decisions on taking measures for eliminating defects were brought. In the process, 2 on-the-spot fines were pronounced, 157 misdemeanour charges were filed, from which only one was resolved, and 2 legal entities and 39 natural persons were fined.

During control of animals (without a certificate) and other products, 77 minutes were prepared, 33 decisions were brought, and 2 on-the-spot fines were pronounced. From the total of 35 misdemeanour charges filed, 22 were resolved.

Within the control of processed products of animal origin, the State Veterinary Inspection has prepared 416 official records on the basis of which 46 decisions were brought, and one filed misdemeanour charge was not resolved.

During the controls of the storage and circulation of products of animal origin, 835 minutes were prepared, and 357 decisions were brought. From the total of 19 misdemeanour charges filed, 3 were resolved, while 2 natural persons and 1 legal entity were fined.

State Veterinary Inspection prepared 2 minutes and brought 1 decision during the control of the storage and circulation of waste of animal origin. It also filed 2 misdemeanour charges, from which 1 was resolved, and 2 legal entities were fined.

The State Veterinary Inspection, during the control of products and medicines, pursuant to the Law on Medicines, Additional Medical Products and Medical Devices ("Official Gazette of the RM No." 21/98) conducted 8 controls and brought 1 decision.

There were a total of 944 decisions brought, and 214 misdemeanour charges were filed.

The consumers also file complaints with the Macedonian Consumer Organisation.

The Macedonian Consumer Organisation received 3,251 consumer complaints during 2003. Out of those, 652 were personal complaints, 2,144 were received by telephone, 387 in written form, and 338 during organised group counselling.

From the complaints received, it may be concluded that most of the complaints, or 1,690 complaints relate to problems the citizens have with warranties and warranty claims; with instructions for use not translated into Macedonian; products with low quality; manufacture services with low quality; problems with travel agencies; not visible price list; non-issuance of receipts, etc. Further, 226 complaints relate to medical patients rights; 53 in the area of insurance and financial services; 416 relate to housing; 483 are complaints on the public enterprises services, mostly concerning the services of Macedonian Telecommunications AD and JSC (Electric Power Company of Macedonia), that still hold a monopoly on the market. In the area of diet and food products, there have been a total of 608 complaints, which have mostly concerned the sales of food products with expired validity; improper declaring and labelling of products; products with low quality; improper storing; counterfeited packaging; 33 complaints related to ecology; and 12 complaints related to counselling for choice of products.

All the complaints submitted to the Counselling Bureaus of the Macedonian Consumer Organisation were documented with an minutes, and the counsellors acted upon them accordingly. After considering the submitted documents and the allegations of the consumer, the Macedonian Consumer Organisation first contacts the trader or the service provider for the purpose of resolving the consumer's complaint.

Pursuant to the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), consumers' associations may intermediate in consumer disputes between traders and consumers relating to products or services bought.

The percentage of successfully resolved cases with the mediation of the Macedonian Consumer Organisation is 25%.

If the mediation is not successful, the Macedonian Consumer Organisation files a complaint before the competent inspection service. In certain cases, which most often relate to problems with public enterprises, the complaint is filed with the Ombudsman of the Republic of Macedonia and the Commission for Protection of Competition. After the measures taken by the inspection bodies in accordance with the legal regulations, information is served to the Counselling Bureaus of the Macedonian Consumer Organisation about the way the consumers' complaints are resolved.

The percentage of cases resolved through the competent inspection bodies, the Ombudsman of the Republic of Macedonia and the Commission for Protection of Competition is 50%.

It means that a total of 75% of the filed consumer complaints were successfully resolved in 2003.

c)

Considering the fact that prior to every import, a document issued by a competent non-customs body certifying that the prescribed conditions have been met needs to be submitted, the customs bodies undertake the following measures:

- keeping of goods under customs surveillance until the required documents are submitted;
- control of the received documents and of their compliance with the goods and other documents;
- rejection or refusal of customs declaration lacking the necessary documents;
- bringing a decision for returning the goods abroad, or confiscation, provided that its entrance is not forbidden, if there are no appropriate documents/evidence submitted within the prescribed period for implementation of customs procedures, with which the goods acquire a status of goods the import of which is banned;
- informing the competent non-customs bodies for cases in which there is a suspicion of misuse;

- informing the competent non-customs bodies for defects discovered after an additional control relating to the issued evidence, their use, or the lack of documents.

There are no data available on the measures undertaken within the customs service.

d)

Pursuant to Article 51 of the Consumer Protection Law ("Official Gazette of the RM" No. 38/04), the damage caused by an unsafe product is compensated according to the regulations stipulated in the Law on Obligations ("Official Gazette of the RM" No. 18/01, 4/02 and 5/03). Since this Law applies to all the damage compensation disputes, even in consumer disputes, the courts do not keep a separate records of consumer disputes, but they are registered as damage compensation disputes in the single register in the civil and commercial court departments. At the same time, this practice is due to the fact that the plaintiffs do not state that the legal basis of their suit is a compensation of damage caused by an unsafe product, unsatisfactory service, a product which does not comply with the declaration, a product with an expired validity etc., but use the general formula "damage compensation". This is the reason that a clear answer relating to the number of cases that have ended before the courts cannot be given.

In practice, most usual examples of such disputes are the ones for damage compensation on the basis of defective products (an airbag in a car has not opened, incorrect functioning of a product within the warranty period, putting into circulation of products with expired validity, lack of instructions for use of the product in Macedonian and its Cyrillic alphabet).

The length of the disputes depends on: the number of parties in the proceedings; the evidence presented with the lawsuit and the response to them; the need of presenting verbal evidence; the need of forensic expertise; the value of the dispute; the direct engagement of the participants in the procedure etc. If the dispute is with a small value, not exceeding 30.000 MKD, and if a proposal for issuing a temporary measure is given, these disputes end up more quickly and last for 6 months at an average for getting a first instance verdict. For the verdict to come into force, the usual period is 1 year from the initiation of the dispute. Other disputes have longer periods of settlement.

The enforcement of judicial decisions, pursuant to the Law on Executive Procedure ("Official Gazette of the RM" No. 53/97, 59/00 and 64/03), is immediate, however, because of the large number of cases waiting on enforcement in general, the enforcement of these disputes also lasts longer. This is also due to the legal possibility for the debtor to use a large number of legal remedies (objections) for which the court has to reach a decision which, again, might be appealed.

e)

The rapid-alert measures are carried out through the Republic Information Centre. For all cases where an evaluation of the product's risk was done the alert was realised through the Republic Centre. A total of 32 alerts were sent during 2003.

The introduction and application of the Rapid Alert System for quick spread of information and taking appropriate measures is in progress. This system will be implemented by a Unit within the Food Directorate, and it officially started its work from 01.01.2005. The main purpose of the programme is protection of consumers' health through establishing a new institutional system for taking professional and administrative measures in the area of food safety, as well as reforming the food control system in compliance with the European Union legislation and in respect of the obligations taken upon with the membership in the WTO. The Food Directorate will have competence over the control of all food products. In compliance with the EU Regulations, this Directorate will analyse its own data, as well as the information from other relevant institutions, and will make a complete data analysis, which will enable characterisation and monitoring of risks which have direct or indirect effect on product and cattle feed safety (in compliance with the Regulations 178/2002/EC and 882/2004/EC). The Food Directorate will implement activities for coordinated actions together with the Ministry of Agriculture, Forestry and Water Economy and the Ministry of Economy relating to food and cattle feed safety, as well as direct cooperation and coordination with the Veterinary Directorate, the Plant Protection Directorate, and the State Sanitary and Health Inspectorate, through activities to be implemented through a scientific and counselling inter-ministerial body (Macedonian Codex

Commission), as well as through the committees which will operate as dispatches of the Food Directorate, and which will include all professional profiles necessary for risk evaluation. For the purposes of all the above, the Rapid Alert System shall be implemented during 2005.

f)

Pursuant to the Consumer Protection Law, the Unit for Consumer Protection within the Ministry of Economy organises several types of meetings and cooperates with the competent inspection bodies, the consumer associations, as well as with the competent state bodies and organisations, and the Macedonian Chamber of Commerce.

The Unit for Consumer Protection within the Ministry of Economy cooperates closely with the Macedonian Consumer Organisation. On the basis of such cooperation, representatives of the legal group of the Macedonian Consumer Organisation have participated in the preparation of the new Consumer Protection Law with their suggestions and proposals. There have been several working meetings on different subjects, and several joint public debates and professional seminars have been organised.

The Counselling Bureaus of the Macedonian Consumer Organisation cooperate with the State Market Inspectorate, hold meetings and consultations on different subjects in the consumer protection area: rapid response upon their complaints; follow-up upon measures taken by the inspectorate; and participate in the bulletin "Consumer" published by the Macedonian Consumer Organisation, and there are efforts for timely undertaking of actions upon the initiatives proposed by the Macedonian Consumer Organisation and relating to consumer protection.

The State Sanitary and Health Inspectorate, the State Market Inspectorate, the Veterinary Directorate, the State Agriculture Inspectorate and other institutions, and the Macedonian Consumer Organisation, closely cooperate in their regular work, inform each other about the established irregularities on the market, and jointly take appropriate measures.

g)

The Ministry of Economy has informed the consumers through the media in a timely manner for all the cases of faulty merchandise put into circulation (as it was the case with the milk, meat, fruit juices, mineral water and other products).

The competent inspection bodies publish the irregularities found and established during the inspections in a transparent way, cooperate with the press and the electronic media through public announcements, press conferences, etc.

h)

During the import of goods the trader is obliged to submit documents before the customs procedures, as it is regulated by the current Trade Law ("Official Gazette of the RM" No. 16/04), and the strengthening of these controls is a constant subject of different meetings between the inspection bodies and the Customs Administration of the Republic of Macedonia. The procedures and the way of ensuring safety control of the products imported into Republic of Macedonia are established separately on these meetings.

Joint meetings of customs and non-customs bodies are held occasionally, as needed, and especially for the cases of adopting or amending the legislation, or when problems during operations are discovered.

On an operational level, the contacts between the competent inspectors of the non-customs bodies and the customs bodies' officers are established on a daily basis.

With the signing of the Agreement on Cooperation Between the Agencies Working on Customs Control Locations on 23.01.2002 between the Ministry of Finance, the Ministry of Interior, the Ministry of Agriculture, Forestry and Water Economy, the Ministry of Health, and the Ministry of Economy, including the bodies within their organisation, as well as with the Public Enterprise for Housing and Business Premises Management, an attempt was made for standardisation and intensification of the

cooperation between those agencies on the border crossings and all the locations with internal customs offices. Local project teams were formed in four test locations, consisting of representatives from every contractual party. The members of the local project team meet at least once a month or when needed, to discuss important issues related to the activities on the test location. The administrative managements of the appropriate contractual parties approve the proposals submitted by the local project teams, unless they establish that the proposals cannot be implemented because of legal or regulatory obstacles. In that case, the superior body elaborates the issue to the management of the contractual party at the test location, including a proposal to amend the proposal in order for it to be legally acceptable. The contractual parties form a Cooperation Committee consisting of high level representatives from the administrative managements of every contractual party. The Cooperation Committee should meet at least once in three months to discuss the approved proposals submitted by the administrative managements, and to propose expanding of their application on all locations in the Republic of Macedonia. If a need arises, or on the basis of the submitted proposals, the Cooperation Committee initiates amendment of the legislation which should enable simplification of the trade and transport, having in mind the need of harmonisation of the legislation of the Republic of Macedonia with the European Union legislation and with other international agreements to which the Republic of Macedonia is a Party.

i)

The control activities of inspection bodies in the Republic of Macedonia are performed on the basis of the legislation and previously approved annual programmes, semi-annual and quarterly operational plans of these bodies.

j)

The State Statistical Office does not have data on injuries caused by usage of unsafe products.

k)

Pursuant to the Consumer Protection Law, the consumer associations, amongst other things, are entitled to express opinions on draft laws and other regulations for consumer protection, and to be informed by the competent bodies on the preparation of regulations in the area of consumer protection.

l)

	2000	in %	2001	in %	2002	in %	2003	in %
1	2	3	4	5	6	7	8	9
Total	127.303.246	100,0	115.878.787	100,0	119.637.287	100,0	138.796.947	100,0
Wholesale	43.127.437	33,9	36.453.186	31,5	38.059.086	31,8	45.025.860	32,4
Mediation in wholesale	1.011.842	0,8	1.046.747	0,9	856.131	0,7	914.570	0,7
Retail trade	28.602.409	22,5	31.332.971	27,0	32.492.067	27,2	38.465.158	27,7
Repairs	267.797	0,2	261.508	0,2	343.588	0,3	281.921	0,2
Other activities	54.293.761	42,6	46.784.375	40,4	47.886.415	40,0	54.109.438	39,0

	indexes 2001/2000	indexes 2002/2001	indexes 2003/2002
	10	11	12
Total	91,0	103,2	116,0
Wholesale	84,5	104,4	118,3
Mediation in wholesale	103,4	81,8	106,8
Retail trade	109,5	103,7	118,4
Repairs	97,7	131,4	82,1
Other activities	86,2	102,4	113,0

Indexes of the sales figures in the retail trade

	2001/2000	2002/2001	2003/2002
1	2	3	4
Nominal indexes	91,6	106,3	113,9
The State Statistical Office does not calculate the sales figures according to the origin of products yet.			
Source - State Statistical Office			

Table: Sales figures of retail trade by product groups			
	In thousands MKD		
	1999	2000	2001
Total	40.413.343	49.105.964	44.996.685
Food products	13.691.644	14.475.592	14.352.091
Tobacco	1.228.031	1.834.795	985.304
Textiles	1.355.682	1.298.815	1.177.191
Leather and rubber	886.905	784.563	490.587
Fuel	110.675	131.587	109.976
Metal products	2.863.657	3.589.739	3.840.428
Porcelain, glass and ceramics	151.962	208.539	136.205
Electro-technical goods	860.970	960.691	834.985
Chemical products	3.839.046	4.552.478	4.582.615
Paper and paper products	530.171	472.030	460.524
Woods products	675.406	1.014.276	550.297
Liquid fuels and lubricants	11.727.816	15.837.159	13.232.831
Construction materials	225.284	544.486	720.546
Other products	2.266.094	3.401.214	3.523.102

The data on retail trade sales figures by product groups are taken from the Statistical Yearbook 2002.

Table: Imports grouped according to intended use of products			
	In thousands \$ US		
	2000	2001	2002
Consumer goods	408.679	355.431	471.189
Food products	154.105	146.797	177.528
Beverages and tobacco	8.201	9.477	9.593
Clothing and footwear	16.605	17.493	19.259
Furniture	12.738	10.448	12.336
Textiles	7.255	6.093	6.600
Medical, pharmaceutical and cosmetic products	49.319	50.415	60.558
Other consumer goods	160.457	114.709	185.315

The data on imports grouped according to intended use of products are taken from the Statistical Yearbook 2003.

3. For which of these product categories have you carried out specific market surveillance activities in the last three years?

- a) Child-care articles (e.g. teething rings, pacifier chains, babywalkers, folding cots);**
- b) playground equipment;**
- c) furniture (e.g. bunk beds, flammability of upholstered furniture);**
- d) do-it-yourself equipment (e.g. ladders);**
- e) leisure equipment (e.g. bicycles, climbing equipment, bounce castles);**
- f) clothing (flammability risks, strangulation risks);**
- g) decorative articles (e.g. imitation fruit, Christmas decorations, candles);**
- h) products containing chemicals (e.g. phthalates in PVC-products);**
- i) products for children, other than toys (e.g. products attractive to children, children's swim seats, playpens);**
- j) cigarette lighters;**
- k) laser pointers;**
- l) medicines.**

a)

With regard to the control of products intended for use by young children, i.e. teething rings, pacifiers, pacifier chains, children's toys, etc., the State Sanitary and Health Inspectorate carries out the control in accordance with the *Rulebook on Conditions Regarding the Sanitary Safety of General*

Consumption Products Allowed to be put into Circulation ("Official Gazette of SFRY" No. 26/83) and the Law on Sanitary Safety of Foodstuffs and General Consumption Products ("Official Gazette of RM" No. 53/91).

A new *Rulebook on the Properties of Children's Toys put into Circulation*, harmonised with the Council Directive for approximation of the regulations of the Member States regarding the safety of toys 88/378/EEC, has been prepared. This Rulebook regulates the mechanical, physical, electrical and hygienic properties of children's toys put into circulation, and also regulates the way of labelling and marking children's toys, with a special emphasis on the need of compulsory warning about the risks presented by their usage, as well as about the ways for avoiding such risks.

In the Republic of Macedonia, there is one production line for children's toys (for children's balls). The raw materials for the production line are imported from Germany and are monitored by the State Sanitary and Health Inspectorate for Border Surveillance. The final product is also monitored by laboratory analyses of product series for the level of migration of heavy metals.

Children's toys are mainly imported from third countries. Greatest quantities are imported from the Republic of China and from the Member States of the European Union. Every shipment imported into the Republic of Macedonia is monitored by the State Sanitary and Health Inspectorate for Border Surveillance at the customs terminals.

The monitoring includes:

- Check up of the vehicle transporting the children's toys (of the sanitary conditions).
- Organoleptic examination of the children's toys:
 - For extrusions, sharp or serrated edges;
 - For their smoothness, they should be coated with a protective coating;
 - For ingredients generally harmful to health;
 - For properties that might cause physical injuries during usage;
 - For properties of the toy's moving parts that might cause physical injuries;
 - For prevention of contact with toys that may be swallowed (for children under 3 years of age);
 - For shedding of natural hairs;
 - For flammability;
 - For explosive elements or substances.

Samples for analysis are taken after the organoleptic examination is done. The laboratory examination checks the migration of heavy metals, the microbiological safety, and the phthalates (depending on the composition and the components of the product). Imported products are put into circulation with a decision of the State Sanitary and Health Inspectorate for Border Surveillance.

The special activities taken by State Sanitary and Health Inspectorate – Border Surveillance Unit in recent years regard the presence of additives from the phthalates group, used as softeners for the products, in the PVC children's toys. The special analyses of samples taken from the market relate to examining for presence of phthalates as additives for softening the product in the toys imported from the Republic of China and the United Arab Emirates. The highly expert and educated personnel, using the modern equipment in the possession of the PHO State Healthcare Institute, has found that the results of the tests for releasing phthalates at room temperature were negative. During the special analyses of PVC children's toys for children up to 3 years of age, special consideration was given to the recommendations of the European Union for presence and release of phthalates from these products.

b)

There is no available data on activities for monitoring playground equipment by the inspection services.

c)

There is no available data on activities for monitoring furniture by the inspection services.

d)

There is no available data on activities for monitoring do-it-yourself equipment by the inspection services.

e)

There is no available data on activities for monitoring leisure equipment by the inspection services.

f)

There is no available data on activities for monitoring clothing (flammability risks, strangulation risks) by the inspection services.

g)

Decorative articles are monitored by the State Sanitary and Health Inspectorate pursuant to the *Rulebook on Quality of General Consumption Products put into Circulation* ("Official Gazette of SFRY" No. 26/83). The monitoring is carried out on every imported and circulated shipment pursuant to the Annual Working Programme of the State Sanitary and Health Inspectorate.

h)

The State Environment Inspectorate monitors the products containing chemicals (PVC products).

The products, semi-products and raw materials, as well as their packaging, are allowed to be put into circulation only if they are labelled – pursuant to the Law on Environment and Nature Protection and Promotion ("Official Gazette of RM" No. 13/03 (revised text)) – for the risk of pollution and the effect they might have on the environment and people's health. Pursuant to the Draft Law on Environment, the producers and importers of chemical substances or products have the obligation, prior to selling or importing, to provide data on their properties and effects, according to which they might be classified, packed and sold; and if the packaging is not solid, to label them completely and appropriately, as determined by this Law or by the regulations adopted on the basis of this law. Dangerous chemical substances or products shall not be sold if their packaging is not solid, completely and appropriately sealed and labelled. The way of classification of pollutants, the form and the structure of packaging, as well as the type of materials that must be used for packaging, the form and the content of the labelling with a noticeable warning sign, and the content of the declaration issued during sales of chemical substances and products will be regulated with secondary legislation.

Pursuant to the Law on Waste Management ("Official Gazette of RM" No. 68/04),

It is expressly prohibited:

- To produce, import or trade in PCBs (Polychlorinated Biphenyls);
- To reuse and process waste PCBs, and
- To fill and refill equipment with PCB.

Legal entities and natural persons in possession of PCBs, used PCB and PCB equipment are obliged to register the quantities, origin, nature and contents of PCB, used PCB and equipment containing PCB with the Ministry of Environment and Physical Planning within a year since the day of the entry into force of the law. At the same time, the legal entities and natural persons are obliged to label the equipment containing or that has contained PCB, as well as to keep records of the treatment of PCB, of the used PCB and the PCB equipment, in accordance with this law and other regulations.

Pursuant to the same Law, the production, importation and circulation of batteries and car batteries containing more than 0.0005 mass percent mercury, including batteries and car batteries incorporated in devices and equipment, is also prohibited. The production, importation and circulation of unmarked batteries and car batteries containing:

- more than 25 milligrams of mercury per cell, except alkaline-manganese batteries;
- more than 0.025 mass percent cadmium;
- more than 0.4 mass percent lead;

is also prohibited.

The State Market Inspectorate, together with the State Environmental Inspectorate, monitors the enforcement of the Law on Waste Management for the part of circulation of products and packaging, labelling of products and packaging, and informing of consumers.

Bearing in mind that the Law entered into force in November 2004, and it will be implemented from 2005, the monitoring measures pursuant to this Law are not yet implemented.

The State Sanitary and Health Inspectorate controls all the products and items that have direct contact with food and are being made of PVC, metal, wood, paper, textiles etc., and laboratory analyses for the possible migration of heavy metals above permitted levels are being conducted. The children's toys are monitored for the presence of phthalates in laboratory. The recommendations of the European Union are implemented in that segment.

i)

No special market surveillance activities have been carried out on products attractive to children, and are not toys, except on plastic products serving as swimming aid for children (swim seats) or plastic children fences which are not produced in the Republic of Macedonia, but are imported from other countries – they fall under the jurisdiction of the State market inspectors for border surveillance and regular laboratory analyses are being carried out for every shipment.

However, there are no records about the number of inspections of the circulation of these products.

j)

There is no available data on activities for monitoring cigarette lighters by the inspection services.

k)

There is no available data on activities for monitoring laser pointers by the inspection services.

l)

In the last three years, in continuity or following a report by authorised institutions or individuals, the Bureau of Medicines – Inspection Supervision Unit has carried out monitoring of medicines. Some medicines were confiscated or withdrawn from circulation for lack of quality, safety or efficiency, i.e. for emergence of unwanted effects, inappropriate packaging and labelling (declaration on the packaging), for lack of certificate for putting into circulation, lack of quality or conformity with the regulations for medicines under special regime, and there has been a number of bans on carrying out business activities.

4. For product-categories for which no activities were carried out: what was the reason that no activities were carried out?

For product categories for which no activities have been carried out, the reasons are as follows:

- Lack of regulations and standards;
- The inspection bodies have no authority;
- Insufficient funds for financing possible testing.

5. For categories for which activities were carried out: choose randomly some of the products falling under the categories of products under question 3 as examples to provide answers to the following questions:

a) Why did you choose these products?

Examples:

i) Accidents involving the product.

ii) Risk reported by the manufacturer.

iii) Risk reported by conformity assessment (testing, certification) bodies.

iv) Risk reported through an alert network.

v) Risk reported through a national alert network (e.g. hospital services).

- vi) Action by consumer associations or an individual consumer.
 - vii) Complaint from a competitor.
 - viii) Information from another country (bilateral contact).
 - ix) Risk reported by customs.
 - x) Special risk covered by a sectoral or seasonal surveillance programme.
 - xi) Random check.
- b) How was the surveillance organised for these products?

Examples:

- i) Timing and frequency of checks (e.g. before placing on the market, during customs clearance, after placing on the market, in use)
 - ii) Locations where the checks were carried out (e.g. places of design, manufacture, packaging, storage, sale, in use, goods transport vehicles, roadside checks, customs control)
 - iii) Control procedures (e.g. documentary or in-situ checks, visual checks (marking, etc.), requests for technical documents, sampling, testing in government laboratories, testing in private laboratories)
 - iv) Resources used (e.g. administrative and judicial authorities involved, numbers of staff assigned, spending)
 - v) Time elapsing between the first check and final decision
- c) Which measures were taken as a result of the checks? (If the measures were temporary, for how long did they apply?)

Examples:

- i) Product deemed compliant.
- ii) Party responsible merely required to bring the product into compliance.
- iii) Product banned from the market until brought into compliance.
- iv) Product withdrawn from the market until brought into compliance.
- v) Product impounded.
- vi) Product ordered to be destroyed.
- vii) Product recalled.
- viii) Information and warning for consumers (how?)
- ix) Recall of the product from consumers (how?)
- x) Civil or penal sanctions (to whom?).

a)

We have chosen the teething baby products, products containing chemicals (PVC products) and swimming aids because they relate to the protection of children and other consumers.

Monitoring activities for these products are carried out in compliance with the safety measures that may be applied for this product category - products coming in contact with little children and present a health risk for this segment of the population. Also, special activities for control of these products are being carried out following the recommendations of the European Union because of the contents of additives which in certain circumstances might cause detriment of health with children.

i)

There are no records that this product category has caused accidents. The continuity in carrying out activities in accordance with the annual plans, and the special monitoring activities carried out by the State Sanitary and Health Inspectorate contribute to the non-existence of accidents caused by these products.

ii)

There are no risks reported by the manufacturers.

iii)

There are no risks reported by the authorised institution for testing and conducting laboratory research on this product category. All laboratory analyses conducted in 2003, 116 on imported products and 2 laboratory analyses on domestic products, are with safe results.

iv)

There is no reported risk for this product category.

v)

There is no risk reported through the Republic Centre for Information, nor through the hospital services.

vi)

The Consumers' Organisation has not taken action, nor has reported anything to the State Sanitary and Health Inspectorate relating to this product category during 2003.

vii)

There are no records.

viii)

We have received information from the European Union (in 1999 and in 2004) with regard to the presence and release of phthalates from children's PVC toys made in and imported from Asian countries.

ix)

There are no records of risks reported by customs.

x)

The surveillance procedure described in the answer to the question 3-a by the State Sanitary and Health Inspectorate for Border Surveillance is carried out through the annual plans and with the seasonal programmes of the State Sanitary and Health Inspectorate, which reduces the risk from these products to a minimum.

xi)

Taking samples for laboratory analyses for part of these products is done by random choice.

b)

i)

All imported products are being checked at the customs terminals or at the border crossings, following the importer's request. For products from domestic production, the products being placed on the market, and in use, the surveillance is carried out pursuant to the Inspectorate's annual plan - in continuity and in compliance with the legislation.

ii)

The State Sanitary and Health Inspectorate is authorised for controlling these products on all locations stated in the question, except for the roadside checks.

iii)

The control procedures include: checking of the documentation stipulated by law or secondary legislation, checking of the producer's in-situ checks, visual check with filing a report, taking samples for analysis and their examination in authorised laboratories.

iv)

There are no activities that involve administrative or judicial authorities regarding the safety of the stated products.

v)

The time elapsed between the first check and the final decision is two days in average, and 10 days in cases of non-compliance with certain conditions.

c)

Examples:

i)

- ii)
- iii)
- iv)
- v)
- vi)
- vii)
- viii)
- ix)

The answer to this question is generally given in the answer to the questions C. b). 3. a),h) l) and C. b). 5. a), b), (for more details see [23 C 3](#)). In the cases when the inspection bodies decide on temporary measures, the irregularities should be eliminated within the period specified by the inspector, pursuant to the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#). At the same time, the inspection bodies are obliged to submit a request for filing a misdemeanour charge against these cases, after which the competent court may decide on a safety measure – ban on carrying out business activities for a period of 1 to 4 years.

- x)

In civil procedure, pursuant to the provisions of the Law on Civil Procedure ("Official Gazette of RM" No. 33/98 and 44/02) and the Consumer Protection Law, there is no possibility for the court to decide on a civil penalty. Such possibility exists for the litigations for copyright and related rights protection, and for the litigations for industrial property rights protection (patents, trade marks, industrial designs, etc.).

6. Have the results of these activities and the experience acquired influenced subsequent market surveillance activities?

In most of the cases, measures taken by the competent inspection bodies for eliminating the irregularities found have had a positive effect on the traders and the producers.

7. Who were informed about the activity and/or the outcome – in general or with regard to specific products (e.g. media, other countries, etc.)?

As far as the activities of the Ministry of Economy, and the State Market Inspectorate are concerned, the public is informed through a standardized procedure applied by the Spokesman of the relevant Ministry. Different communication channels for distribution of information are applied, depending on the type and purpose of information.

The exchange of information with media is carried out through: answering questions, submitting service information, occasional briefings etc.

The citizens are also communicated through placing the information on the Web page of the Ministry of Economy.

8. What practical difficulties were encountered in carrying out the activities?

In general, the inspection bodies always put maximum efforts in terms of determining and removing the deficiencies of certain products, determined during supervision.

The main problem of the inspection bodies, in carrying out activities and performing the surveillance is lack of funds necessary for equipment, which would contribute towards better and more efficient results concerning the inspection operations and supervision.

D. SPECIFIC QUESTIONS ON THE PROTECTION OF ECONOMIC INTERESTS OF CONSUMERS

9. If public authorities exist to protect the economic interests of consumers, please specify the powers at their disposal and give some examples of activities carried out.

Within its competencies, pursuant to the Consumer Protection Law ("Official Gazette of RM" No. 38/04), see [23 Annex 01](#), the State Market Inspectorate also acts on issues regarding the protection of the economic interests of the consumers.

If the inspector, in the course of supervision, determines that:

- upon the request of the consumer, the trader does not return the amount paid for the purchased product that was returned;
- the trader makes the purchase of a particular product subject to purchase of other products or in other way conditions the purchase and sale of products;
- the trader does not give to the consumer the reward without delay, when such reward has been promised to the consumer in case of purchasing the product or providing the service;
- the trader, when selling bulk products, does not pack them in an appropriate packaging;
- the trader does not satisfy the consumer's request when the customer is sold a defective product.

When the consumer's request is not satisfied, and the fault is discovered within the warranty period of products for which warranties are provided or within 6 months for products with no warranty, and the trader does not prove that the faults of the product have been caused by infringement of the rules for safe keeping by the consumer or third persons, the consumer has the right to request, by their own choice:

- free of charge removal of the defects of the product or reimbursement of the expenses for removal of the defect;
- proportional reduction of the retail price;
- replacement of the product with appropriate product with the same trademark, type, industrial design or designation of origin and geographical destination of the product;
- replacement of the product with appropriate product with different trademark, type, industrial design or designation of origin and geographical destination of the product, with appropriate reduction or increase of the retail price; and
- Cancellation of the contract, return of the paid amount and compensation for the suffered damages.

If the consumers do not exercise their right with the trader, they submit a claim to the State Market Inspectorate directly, or through the Macedonia Consumers Organisation. State Market Inspectorate, after an inspection surveillance procedure, and in case they determine an infringement of the legal provisions, brings a Decision that orders and determines a period for removal of the defects; and in case the determined defects are not removed in the prescribed period, it will decide upon a ban on carrying out business activities for 30 days.

If for a second time during the same year it is determined that the trader did not comply with the decision, the inspector will bring a Decision for banning of carrying out business activities for 90 days. The brought decisions may be appealed, but the appeal does not postpone the execution of the Decision.

The Law also provides penalties for the infringement of the legal provisions; the State Market Inspectorate files a misdemeanour charge with the competent court.

The consumer's claims usually relate to complaints on products about the quality, e.g. of mobile phones, electric household appliances or services provided, and usually they are settled with the replacement of the products.

Example:

1. The customer complains: the purchased TV set did not function right after the purchase.
 - Actions taken by the inspector:
 - After the establishment of the defect, and confirmation of the consumer's claim, the amount for the purchased product is reimbursed.
2. The customer complains: The purchased product, a mobile phone, has technical faults that make it dysfunctional.
 - Actions taken by the inspector:
 - The consumer's claims are confirmed, and the product is replaced by a new one.
3. The customer complains: The electrical stove does not function.
 - Actions taken by the inspector:
 - The consumer's claims are confirmed, and the product's defect is removed.

The consumer's claims are confirmed, and the complete amount for the purchased product is reimbursed.

10. Please provide details on enforcement of legislation in the area of financial services, in particular on consumer credit.

The protection of users of certain financial services is provided on the basis of the Law on Deposits Insurance Fund ("Official Gazette of RM" No. 63/00, 29/02, 43/02, 49/03, and 66/03), the Banking Law ("Official Gazette of RM" No. 63/00, 51/03, and 85/03), the Law on Supervision of Insurance ("Official Gazette of RM" No. 27/02), the Law on Leasing ("Official Gazette of RM" No. 4/02 and 49/03), the Law on Fast Money Transfer ("Official Gazette of RM" No. 77/03 and 2/04), the Law on Contractual Pledge (Official Gazette of RM No 05/03) ("Official Gazette of RM" No. 5/03), and others.

More details about the Deposit Insurance Fund are given in the answer to question II. Financial services, A. Banking sector, General questions, 3. Legal framework - Conditions for collaboration, under No. 10 from Chapter 3 – Free movement of services, (for more details see [03 II A 3 10](#)).

Pursuant to the Law on Deposits Insurance Fund, a total of 102.640.177.50 MKD (approx. 1,6 million Euros) were paid off for the insured deposits by 10 October 2004, from the total sum of 109.281.083.50 MKD (approx. 1,8 million Euros) that are supposed to be paid off by the Fund for Deponents - Natural Persons from banks and savings banks with revoked founding and operating licenses. The unpaid sum is due to the natural persons' failure to claim their funds.

The Banking Law regulates especially the protection of the savings deposits. A business bank is obliged to determine the ways and conditions for accepting and withdrawing savings deposits in its acts, and to display on a noticeable place in the teller's premises copies from the National Bank's Governor decision for granting of a founding and operating license, the interest rates in effect, the general terms of handling the savings deposits, and the type and amount of guarantee for the savings deposits.

If the bank fails to issue a special document – a savings book for the denar and foreign exchange savings deposits to the natural persons, the National Bank takes a decision on revoking the part of the license regarding acceptance of savings deposits.

The National Bank of the Republic of Macedonia permanently controls the operation of the banks and their adherence to the legal obligations and supervision standards, and takes measures against banks which do not adhere to them.

The National Bank, within the regular supervision of the banks' operations, undertakes measures to prohibit the acceptance of savings deposits against the banks which have endangered the timely implementation of commitments towards the creditors (deponents) of the bank. Thus, in 2000, one bank was prohibited to perform financial activities for a given period; in 2001 the measure for prohibiting of acceptance of savings deposits was undertaken against one bank; and in 2002 this measure was undertaken against two banks, while one bank was prohibited to accept new or prolong the existing deposits of natural persons.

For not adhering to the provisions of the law regarding the protection of the depositors, the Banking Law provides the following penalties:

- An employee of the bank who, exercising their duties, with premeditation does not issue a savings book or other appropriate document, depending on the kind of the deposit, shall be sentenced to three to five years of imprisonment;
- Also, the bank shall be fined for infraction with the sum of 100.000 to 300.000 MKD, and the Executive Body of the bank and other persons with special rights and responsibilities in a bank shall be fined with the sum of 10.000 to 50.000 MKD, and shall be prohibited from performing executive duties in a bank for a period of one year if: a) they fail to issue a savings book to natural persons; and b) do not publicly display the conditions for operating with savings deposits in the teller's premises.

The protection of insurance services users is regulated by Article 50, paragraph 1, point 7 of the Law on Supervision of Insurance, which stipulates that the insurance brokerage shall, when concluding the insurance contract, notify in writing the person on the right to lodge a complaint with reference to insurance undertakings and insurance brokerages with the Ministry of Finance. No complaints have been lodged with the Ministry of Finance since the Law has entered into force (April 2002).

The credits in general, including consumer credits, as well as the credits on the basis of lien on securities, are regulated by the provisions of the Law on Obligations ("Official Gazette of RM" No. 18/01, 3/02, and 5/03). The security of loan and credit agreements is regulated by the Law on Contractual Pledge (Official Gazette of RM No 05/03). Banking financial deposit, banking current accounts, safe agreements, and banking guarantees are regulated by the Law on Obligations (Article 1127 of the Law on Obligations stipulates that the provisions of Articles 1074 to 1126 are suitably applied to legal persons other than banks, if they are authorised for performing certain banking operations).

Non-purpose credits are credits for which the approval is not conditioned with submitting special documents for proving and establishing the purpose of the credit, and they are used in cash. Our banks offer: cash credits; cash credits with a pledge on foreign exchange savings deposit; cash credits with a pledge on bonds issued by the Republic of Macedonia, on the basis of a foreign currency savings deposit.

Purpose credits are: housing credits, credits for business premises and office equipment; passenger vehicles credits and credits for other purposes.

The eligibility for these credits is conditioned with certain formalities.

The bank, with the contracts, always retains the right to change the interest rates according to the internal Bank Ordinance on Interest Rates.

The banks in the Republic of Macedonia conclude contracts with certain traders for crediting the products bought from their shops.

Most of the banks and savings banks grant credits with liens on citizens' cheques or other securities.

With the contract for a credit on the basis of lien on securities the banks approves credits with defined amount through securing a lien with securities belonging to the user of the credit or to a third person that agrees on that.

If the user does not return the granted credit after due for payment, the bank may sell the liened securities.

Cash non-purpose credits are also the credits granted on the basis of lien on foreign exchange savings deposit.

Banks also grant cash non-purpose credits on the basis of lien on bonds issued by the Republic of Macedonia on the basis of foreign exchange savings deposits.

The banks determine the amount of the individual credit on the basis of the average market price of the bonds in the previous month.

The time limit for repayment of these credits is most often equal or less than the remainder of the time limit for repayment of the bonds.

The right for using credits belongs to natural persons owning the state bonds, or to natural persons to whom the owners have transferred the ownership.

Housing credits are most often granted for the following purposes:

- Buying newly constructed or old apartments from legal entities or natural persons;
- Construction (new construction, completion of construction, extension of a building, thorough reconstruction) of family residential buildings.
- Construction of apartments in residential buildings by joining funds.
- Adaptation of apartments, or family residential buildings, for improvement of the functions and the standards in the apartment.

The time limits for repayment extend to maximum of 10 years.

Banks also grant credits for buying passenger vehicles from car selling companies that have concluded special contracts with the bank.

The amount of the credit is established on the basis of user's credibility. The maximum amount of the credit cannot be higher than the sum of the invoice minus the participation.

For passenger vehicle credits a participation of 30% from the buyer is required. The time limit for repayment varies from 48 to 60 months. The interest rates on these credits are most often not higher than 20% per year.

The banks consider natural persons credible if they can cover the monthly annuity of the granted credit with their free monthly net income.

The market in the Republic of Macedonia also offers the service of financial leasing, which is regulated by the Law on Leasing. The service of financial leasing may be used by natural and legal entities alike. With regard to the function of rights protection of the users of the financial leasing service, the law stipulates that the leasing user, in case of leasing in which the Lesser selects the Supplier, i.e. the subject that provides the object that the user will use on the basis of the leasing contract, the Lessee may require cancellation of the leasing contract after previously informing, in written or electronic form, the Lesser, if the delay in the delivery of the object exceeds 30 days from the day the object from the leasing contract was to be delivered (Article 11, paragraph 3 of the Law on Leasing). In cases of acquiring leasing objects like these, the Lesser and the Supplier are held equally responsible against the Lessee for any damage with respect to the quality of the object of the leasing, the correctness of the operation, replacement or reparation of a defect and installation of the object (Article 7, paragraph 6 of the law). There are also penalty provisions for the persons not adhering to these obligations (Article 18 of the Law).

The protection of rights of the users of financial leasing is also secured through the obligation of the Lesser to register the object of the leasing within five working days from the day of signing the leasing contract with the special register kept at the Central Registry of the Republic of Macedonia.

Pursuant to the Law on Fast Money Transfer, the providers of the fast money transfer services charge a fee for the service upon a determined tariff. The service provider is obliged to display the tariff on a prominent place in the premises where the fast money transfer is conducted.