Government of Montenegro

Ministry of Economy

Questionnaire

Information requested by the European Commission to the Government of Montenegro for the preparation of the Opinion on the application of Montenegro for membership of the European Union

– ADDITIONAL QUESTIONS –

28 Consumer and health protection

Minister: **Branko Vujovic**

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28: Consumer and health protection

I. CONSUMER PROTECTION

A. Horizontal aspects

1. (Ref. to Q 8): Please provide information on membership of the 2 consumer organisations. What is the criterion in the national legislation for a representative CSO (what is needed for an organisation to be called a national representative organisation of consumers)? What is their annual average budget since establishment and for the last year and what are the type and proportion of budget revenues?

NGO "CEZAP" consists of 77 members, and NGO "ECOM" consists of 54 members. Each member of these organisations is a physical entity.

Special criteria in order for an organisation to be recognised as the national representative consumer organisation are not defined in the national legislation of Montenegro.

We will use this opportunity to repeat a part of the answer to the previous question no. 8, which states that if an NGO wants to have consumer organisation status, it is obligatory for an NGO to register itself into the Register of consumer organisations with the Ministry of Economy, as the line ministry for consumer protection (Article 120, Law on Consumer Protection). Additionally, the same Law (Article 123) stipulates that in order for an organisation to be financially supported by the state, it has to have at least 50 members (physical entities).

Consumer organisations budget:

NGO "CEZAP", since its establishment, has an average income, as follows:

1) Average annual income since the establishment:
    - Average income for the 2000 - 2001 period was DM 46.835;
    - Total income for 2003 was $ 25.380;
    - Average income for the 2003 – 2008 period was € 33.529;
2) Last year budget:
    - Total 2009 income was € 39.478.

All of the abovementioned incomes, are made on the basis of project donations, out of which € 20.000 are Budget-related, where the Ministry of Economy, through tender procedure, allocated this funds for the realisation of particular activities from the National Consumer Protection Programme, and its strengthening as well. All of the funds are spent for the projects mentioned in the answer to the question no. 8.

NGO "ECOM" started its activities, in the field of consumer protection in 2008, and made the 2009 income to the amount of € 19.000. The funds are Budget-related, where the Ministry of Economy, through tender procedure, allocated this funds for the realisation of particular activities from the National Consumer Protection Programme, and its strengthening as well. All of the funds are spent for the projects mentioned in the answer to the question no. 8. The Government provided the NGO with premises, which are state-owned.

2. (Ref. to Q 12): Please provide more details on the joint liability.

As it is already mentioned in the previous answer to this question, when multiple producers are responsible for a damage caused by irregularity of a product, and in the case that the damage was

caused by a third person, the provisions of the Law on Obligation Relations are applied, and according to them the responsibility of these entities is joint.

It means each joint responsibility debtor is responsible to the creditor for the entire obligation and the creditor may demand its fulfilment until the obligation is fully met, and when one of debtors fulfils the obligation, it is terminated and all of the debtors are freed.

Multiple joint debtors can have their debts set with different deadlines, under different conditions and other differences.

The Law stipulates the possibility of compensation and each joint debtor can call on the compensation that was done by his co-debtor.

Joint debtor can, claim of his/her co-debtor to creditor, compensate with creditor's claim, but only for the debt proportion of that co/debtor in joint responsibility.

Debt release, done upon the agreement with one joint debtor, releases other debtors from the responsibility as well.

But, if the release was done in order to release from the responsibility only one of the debtors, the joint responsibility will be decreased by that debtor's amount, and other debtors are responsible for the rest of the responsibility.

3. (Ref. to Q 18): Please confirm whether there are plans to amend the newly adopted General Product Safety Law and specify which subjects require amending, i.e. which Directives and with which clauses?

Yes, we plan to amend the Law on General Product Safety in order to harmonise the Law with Regulation 765/2008. Since this Regulation abolishes Regulation 339/93, the amendments will mainly be oriented towards the provisions that transferred Regulation 339/93 into the Law, and they are related to the cooperation of customs and market supervision body (Article 15). Additionally, the Law will incorporate Regulation 765/2008 provisions, which, in order to attain higher level of protection from products representing serious risk, change Directive 2001/95/EC. (For instance, Article 8 Paragraph 3). Moreover, amendments will take into account principles from Article 16 – 27 of Regulation.

Preparation of amendments of the Law is planned within the IPA 2010 project, and the start of its realisation is expected for the second half of 2011.

4. (Ref. to Q 19): Please provide answers on the following:

a) Please comment on the resources (different than the human resources which are already presented) of the inspectorates. Please provide information on the information systems used to register inspections and results and on their use in risk assessment.

Ministry of Economy (Market Inspection):

In the Market Inspection the networking of IT equipment is currently being performed (major part was received within CARDS 2006 funds) in all offices (headquarter in Podgorica and on the rest of 16 offices in other Montenegrin cities), and creation of programme for the work of the Inspection as well. Application finish is expected by the end of 2010 2nd quarter. The information system will provide monitoring of the Inspection result according to particular regulation groups, including the fields of consumer protection, products safety etc., which will be beneficial in the risk assessment. This information system will be the basis for the development of the information exchange system

on dangerous products at the state level, in accordance to the Decree on information exchange manner of risk-presenting products, since the Market Inspection is the contact exchange point.

The Market Inspection is testing consumer complaint monitoring programme, done by EU TRIM-MNE project, and it is planned to include it into the informational system which is currently under construction.

Ministry of Health (Healthcare-sanitary Inspection):

Information system in the field of inspection supervision of the Ministry of Health is not yet established. In the field of food safety, the preparations were made for the creation of data/register bases containing approved projects for the subjects under the competence of sanitary inspection. We have prepared a request for technical assistance within TAIEX to create the abovementioned data/register bases.

Environment Protection Agency (Environmental Inspection):

The Agency possesses RAIS (Regulatory Authority Information System), i.e. the information system providing radiation source regulatory control. This programme helps Regulatory Authority regarding the implementation of particular activities from the scope of their jurisdiction such as: keeping inventory records of radiation sources, authorisation, inspection etc. RAIS can tackle different range of data from the following fields:

- Plants (name, registration number, address, responsible person ...),
- Radiation sources and appropriate equipment (generators, equipment, closed and open radiation source),
- Authorisations (apparatus production, export, import, isotope production, storage, transfer, transport, usage),
- Inspection (plant, date, source, irregularities, inspector …),
- Law implementation (plant, date, type of measure, authorised person who implemented the measure, inspection …),
- radiation events (date, data, location, plant, is it off site or on site, event and source analysis, employees, patients, doses, reporting …),
- Professionally exposed persons (status, annual doses, attended courses, professional qualifications),
- Technical service units,
- Producers and models.

It is planned to establish the information systems for other fields of environment protection which is going to incorporate the Cadastre of Environmental Polluters. The Rulebook on the Cadastre of Polluters is in drafting procedure. Environmental Inspection, for the time being, is collecting particular data which will be used as the basis for the establishment of Cadastre.

Phytosanitary Administration (Phytosanitary Inspection)

The Inspection is partially equipped with IT equipment. It is planned to establish Phytosanitary information system within the proposed 2010 IPA Project - Strengthening of the Phytosanitary of Montenegro. The Project envisages networking of already set up registers in the Phytosanitary filed, networking of Phytosanitary Administration, laboratories and Phytosanitary Inspection (IT System for Phytosanitary Inspection at border crossings).

Bureau of Metrology (Metrology Inspection):

The Inspection has IT networked equipment, but it still lacks the information system for the Inspection work.

b) Please comment on the timing of the legal proceedings in case of breach of legislation on consumer protection.

In the case of the Law and other regulations violation from the consumer protection field, several procedures are applicable: administrative, misdemeanour, court and out of court (arbitration).

Administrative procedure

When a competent inspector (according to official duty, or consumer complaint) in the procedure of inspection examination, determines the regulation violation, he/she shall take measures in accordance to the Law on Inspection Supervision and other special laws.

Depending on the gravity of violation, and if a subject of supervision gave his/her consent, the inspector through the record will draw the subject's attention to the irregularity and shall define an appropriate deadline for its removal. The subject of supervision shall notify the inspector regarding taken measures in the written form, within the period of seven days from the day of deadline expiry defined for the removal of irregularity. If the subject of supervision, within the defined deadline, completely removes the irregularity noted by the inspector, the inspector shall terminate the procedure, otherwise, he/she shall order by written decision the removal of the abovementioned irregularities.

If the inspector did not opt for administrative measures and actions, s/he shall order by written decision or, exceptionally by oral decision, when s/he thinks the manner is the appropriate one for the removal an imminent danger for life and health of people, property of higher value and other public interest. Within the period of three days from the day of issuing oral decision, the inspector shall issue the written decision as well.

Deadline for filing a complaint to the decision of an Inspector is 8 days from the day of decision submission. Appeal on the decision shall not postpone the execution of decision (Article 40, Paragraph 3, the Law on Inspection Supervision). Exceptionally, it can be postponed until the adoption of decision on appeal if the nature of relation allows that, if the postponement is not against the public interest and if the execution postponement can cause damage to the subject of supervision. If the subject of supervision asks for the execution postponement, the inspector shall decide upon that with the conclusion within the period of three days from the day of complaint submission.

Complaint decision procedure is regulated by the Law on General Administrative Procedure, and it can last no longer than two months from the day of complaint reception. Against a final ruling, a party can start the procedure before the Administrative Court, which is defined by the Law on Administrative Dispute.

For the determined irregularities in a supervision examination which represents misdemeanour, the inspector may issue on site fine, in prescribed cases, or submit request for starting the misdemeanour procedure before a competent court

Deadline for the fine payment which is issued on site by the inspector is three days from the issuance day, and the height of the fine ranges from twofold up to fivefold amount of the minimal salary in Montenegro for an entrepreneur, or to the amount of one up to threefold amount of minimal salary in Montenegro for the responsible entity within the legal entity and for physical entity as well

After the reception of a complaint the competent inspections shall immediately start the inspection supervision procedure. Administrative procedure (without a complaint) on average lasts from 10 to 15 days.

Misdemeanour procedure

Request for starting a misdemeanour procedure shall be submitted by an inspector, not later than 60 days from the day of misdemeanour notification, to a body competent for misdemeanour procedure in the line ministry. The deadline for ending a misdemeanour procedure is defined by the Law on Misdemeanours and lasts up to two years. The length of misdemeanour procedure

within this time limit is from three months up to two years and it depends on process activities necessary for each individual subject.

Court procedure

Courts do not keep records which provide special monitoring of subjects related to laws and other regulations violation from the field of consumer protection, and, consequently, it is not possible to provide data regarding the duration of such procedures.

Out of court procedure (Arbitration)

Consumer dispute decision procedure before the Panel (arbiter) of Arbitration Committee for out of court consumer disputes decision lasts up to 30 days from the day of consumer complaint. Exceptionally, reaching of the decision can be postponed up to 30 days more.

c) How is the information between market surveillance bodies exchanged? What is the current capacity and what are the plans for future?

Obligation of international cooperation of inspection bodies and cooperation with other bodies in the performance of inspection supervision, is regulated by the Law on Inspectional Supervision (Article 63), and information exchange between the bodies for market supervision is regulated by the Law on General Product Safety /more details in the answer to the main question 20 e), f), h)/.

Information exchange between the bodies for market supervision, including Customs, on the basis of the Law on General Product Safety, is regulated into more details with the Decree on the manner of information exchange for products which present risk (Official Gazette 13/10). This Decree provides legal framework for data exchange on dangerous products between the supervision bodies in Montenegro. The question of coordination of market supervision and information exchange between the supervision bodies is addressed in the Market Supervision of Montenegro, which was adopted by the Government on 5th November 2009, and the Strategy will be implemented in the next period.

Currently, information exchange between the market supervision bodies is performed through written media and distance communication devices (fax, e-mail, telephone, etc.).

In Market Inspection, which is, in accordance to the Decree on the manner of information exchange for products which present risk, contact point for data exchange, the process of IT equipment networking and establishment of Information system are currently being performed. The Information system will be the basis for development of the system for information exchange for products which present risk at the national level, in accordance to the abovementioned Decree.

d) Please provide general information on the compliance with Regulation 765/2008.

In the answer to the additional question no. 3 it is already mentioned that Regulation 765/2008, the part of market supervision and control of products imported for the third countries, shall be completely included into the Law on General Product Safety through amendment procedure.
Respect of principles from this Regulation, with the abovementioned parts, with a view of health protection and safety or protection of other public interests from products representing serious risk, is already enabled through several laws and the Strategy of market supervision in Montenegro as well. This is related to the proscribed rapid intervention measures by competent bodies, which include the removal of such products from the market, their recall and prohibition of entering the market. Apart from the Law on General Safety, these measures are included into other laws such as:
The Law on Plant Nutrition (Official Gazette 48/07 and Official Gazette 76/08), in Article 8, stipulates the possibility if, through scientific and technical know-how, determine that plant nutrition

presents risk for the health of people, animals, plants and environment, although it may meet the conditions stipulated by the Law, it may be temporarily or permanently prohibited for production and circulation, or define special conditions for production, circulation and application of such plant nutrition.
Law on Plant Protection Products (Official Gazette 51/08), in Article 12, stipulates that the plant protection products shall have their application prohibited or circulation limited, when the procedure of implementation of stipulated measures and procedures from the field of environment protection and new scientific and technical know-how, provides evidence the registered plant protection product is dangerous for the health of people, animals, plants and environment. Additionally, the plant protection products, containing active substances whose circulation is limited or prohibited, shall have their circulation/application prohibited or limited.

The significance of the Abovementioned Strategy of market supervision is on the respect of Regulation is that the Strategy is based on the New package for goods in internal market and EMARS Project Reference book. The translation of the Strategy is attached to the answer to the additional question No.15 (related to the question No. 28) Chapter 1 – Free movement of goods. In this manner the bodies participating in market supervision will strengthen their cooperation and coordinated supervision. Prior to that, we will implement, with the support of IPA 2009 and IPA 2010 programme, consumer protection component and market supervision, and the first one starts in April of this year.

Respect of Regulation, regarding the accreditation, can be partially found in the answer to the following additional question, and it is also addressed in Chapter 1 – Free movement of goods.

e) Please provide information on the testing facilities (access, conditions and procedures; availability; how many tests per year, etc.?).

In accordance to the Law on Inspection Supervision an inspector may take samples, if it is necessary to determine, through the inspection supervision procedure, whether products in circulation match regulated or declared content, i.e. quality.

„Article 43 Sampling procedure

While sampling an inspector shall:

1) under the same condition and at the same time, take maximum three samples in the quantity necessary for examination (for the first analysis, the second analysis and super analysis);
2) make record on sampling;
3) seal samples and mark them properly;
4) the sample for the first analysis immediately submit to the competent expert institution, and keep the second and third sample in appropriate conditions;
5) immediately notify a subject of supervision on the results of the analysis;
6) on demand of the subject of supervision immediately submit the second sample to other expert institution;
7) by special conclusion, determine the amount of costs made in the sample analysis procedure, who they shall be paid to, and until when, in the case a sample does not meet required standards.

Article 44 Presumption of consent

If the subject of supervision, during the sampling procedure, does not demand instantaneous taking of second analysis sample, s/he cannot disprove the taken sample analysis results.

Article 45 Disproval analysis results

The subject of supervision may disprove the first sample analysis result by the request for the performance of the second sample analysis (taken at the same time and same manner), within the period of three days from the day of the deliverance of the first sample analysis results.

It shall be assumed the subject of supervision agrees with the first sample analysis results if the request from Paragraph 1 is not submitted within the prescribed time.

Should the second sample analysis result differs from the first sample analysis results, the second sample analysis result shall be valid.

The second sample analysis shall not be submitted to the expert institution which had performed the first sample analysis.

Article 46 Super analysis

If the inspector disagrees with the second sample analysis results, s/he may request, within the period of three days from the delivery of the second sample analysis results, the performance of super analysis, except in the cases the first and second sample analysis results are of equal value.

Super analysis cannot be sent to the expert institution which had performed the previous analysis, except in the case the other authorised institution for the performance of such analysis is nonexistent, and if both the inspector and subject of supervision agree to trust the new analysis the one of the institutions that had already performed the analysis.

Article 47 Analysis costs

Analysis costs shall be borne by the subject of supervision, if it is found that samples do not meet prescribed standards.

Analysis costs shall be borne by a competent inspection body if it is found that samples meet prescribed standards“.

Samples are taken in accordance to specific technical regulations depending on the sampled product type.

Samples, together with the Record on taking, are submitted to some of the referent bodies in order to assess if the standards are met. Procedures and other conditions related to the bodies for assessment are part of both the strategic documents of the Accreditation Body of Montenegro and the principal activity of this national body for accreditation /described into more details in Chapter 1 – Free movement of goods/. In the Law on Accreditation, in Article 15, accreditation is a necessary condition for authorisation.

Accreditation Body of Montenegro has accredited 8 bodies for conformity assessment (6 laboratories for examination, 1 laboratory for calibration and 1 control organisation), which provides valid examination results, i.e. control from the important fields of accreditation (such as metallurgy, environment, road traffic, fuels and lubricants ...). Currently in the procedure of accreditation are the bodies for conformity assessment from the fields of examination of: foodstuffs, general use objects, electric installations, ferrous and non-ferrous materials, lifts attesting, and noise.

Law on Technical Requirements for Products and Products Conformity Assessment with the prescribed requirements, in Article 19 states the following:

“(1) Competent Ministry shall adopt the decision on designation or authorisation of the body for conformity assessment, which can be time-limited.
(2) The decision from Paragraph 1 of this Article is related to the request of a legal entity meeting the conditions defined by technical regulation for the performance of conformity assessment activities.
(3) While adopting the decision from Paragraph 1 of this Article, the competent Ministry shall establish if the legal entity from Paragraph 2 of this Article meets the conditions for the performance of conformity assessment activities.
(4) In the procedure of assessment if the conditions, from Paragraph 3 of this Article, are met, the competent Ministry shall assess the technical competency from accreditation procedure or from other equally important procedure as well.

(5) Decision from Paragraph 1 of this Article shall be final and an administrative dispute cannot be instituted against it".

Report on annual number of tests:

In 2008 the competent inspection took 89 samples of toys, out of which 8 samples did not met the required standards. Sample analysis was performed by the referent institution the Public Institution Centre for Ecotoxicological Research in Montenegro - Podgorica (CETI).

In 2009 the competent inspection took 29 samples of toys, out of which 4 samples did not met the required standards. Sample analysis was performed by CETI.

In 2009 the competent inspection took 26 samples of oil-derived liquid fuel, out of which 6 samples did not met the required standards. Sample analysis was performed by the referent institution the „Jugoinspekt Beograd", joint-stock company – Beograd.

In 2009, 30.201 controls of particular goods radioactivity were performed and 135 controls of ionising radiation sources that are used for medical purposes – x-ray generators.

The competent institutions for measuring-testing the level of radiation are: CETI, The Institute for Ferrous Metallurgy in Nikšić and Faculty of Natural sciences and Mathematics in Podgorica. They work according to the adopted procedures in accordance to the legal regulations.

Examinations from the phytosanitary field, on the basis of delegated competencies, are performed by:

- The Institute for Public Health in Podgorica: physical-chemical food testing,
- CETI: physical-chemical tests,
- Biotechnical Faculty in Podgorica, within which operate:
  - Phytosanitary Laboratory – Centre for Plant Protection (diagnostic examinations of harmful organisms for plants and plant products and examination of biological efficiency of pesticides);
  - Laboratory for seeds - Centre for field crops, vegetable growing and forage plants (testing and determining the quality of agricultural plants seed material);
  - Laboratory for seed and seedlings – Centre for viticulture, oenology and fruit growing in Podgorica and Centre for subtropical cultures in Bar (research and quality assessment of seedlings).

The Institute for Public Health recommends and implements measures regarding the control of the regularity of foodstuffs, and general use objects and controls hygienic correctness of drinking water, surface and waste waters and performs microbiological and parasitical, chemical, biological, toxicological, biochemical and other laboratory analysis. Annually, the laboratories microbiologically examine about 7500 samples of foodstuffs and general use objects and about 5000 samples of drinking water, and 6500 samples of foodstuffs and general use objects and 5500 samples of drinking water through physical-chemical analysis. Apart from that, the laboratories examine the quality of waste waters, soil and air.

The number of conformity assessment bodies used for particular groups of products in Montenegro is given in the answer to the additional question no. 19.

f) Is there a place where information on dangerous products is published in the language(s) of the population for general use?

Information regarding dangerous products are published through print (daily, sold in whole of the territory of Montenegro) and electronic media, and the bodies which have their own websites also use this possibility to inform the public (more details can be found in the answer to the main question no. 19f, 20g, 25)

Information for medicines which are against the defined regulations is published in the national language on the website of the Montenegrin Medicine Agency: http://calims.me/.

Information for environment is published in the national language on the website of the Environment Protection Agency: www.epa.org.me.

Additionally, other bodies, once they have set up their websites, shall publish information on dangerous products. /see answer to the additional question no. 20/

We want to repeat that the inspection body which determines that there is a dangerous product in the market has legal obligation to inform the public (more details in the answer to the additional question no. 20).

5. (Ref. to Q 21): Please specify the number of control inspections exercised per listed product groups for those groups that have been subject to market surveillance.

- for the products under (a) and (i), including toys, in 2008 and 2009, the total of 757 and 562 controls was performed respectively. For the performed control of these products there is no special record keeping for the given groups, but it is within the record on controls of toys.
- for the products under (b), (c), (d), (e), (f), (g), (j) and (k) there is no special record keeping, but it can be found within the total number of controls.
- for the products containing chemical substances (h) there is no special record keeping, but they are registered within the performed controls for toys and materials that are in contact with food.
- for control of medicines (l) in 2008, the data are given in the previous answers (to the question No. 21(l)).

Medicines control in 2009:

The Montenegrin Medicine Agency, in accordance to the Law on Medicines (Article 77-81a), have performed the following types of medicines quality control:

Control of medicine quality prior to its entering the market circulation:

- in the procedure of licence issuance for entering the market circulation (the registration procedure), 152 medicines were controlled,
- quality control of the first batch of medicine after the licence for entering the market circulation has been issued (the first batch appearing after the medicine registration). Currently we are performing the sample control of the first batch of medicine made by domestic producer NOVIT PHARM (in the Medicines and Medical Devices Agency of Serbia), for 5 medicines (60 samples each),
- obligatory quality control (repeated control) of each batch of medicines which are categorised as risk-bearing medicines: immunological medicines, radiopharmaceutical medicines, and medicines derived from blood and plasma (a producer, apart from the control in its own laboratory, for the release into market circulation, has to perform another control in some of the independent laboratories (the Medicines and Medical Devices Agency of Serbia or Agency for Medicinal Products and Medical Devices or OCABR (Official Control Authority Batch Release) EU certificate).
- All medicines from the category of risk-bearing medicines which are imported in Montenegro in 2009 had to have a proof of repeated control for each medicines batch.

Control of medicine quality after the release (after medicine registration). This control is performed in the cooperation with the competent inspection of the Ministry of Health, which, on that recommendation of the Agency, can temporarily or permanently withdraw a medicine or medicine batch from the market:

On the basis of information from regulatory bodies from other countries, EMA, producers and healthcare workers, the Agency has recommended to the competent inspector the following measures:

- Temporary withdrawal of one batch of medicine (vaccine) – after a healthcare workers reported his/her doubt regarding quality (the set was reintroduced into the market after we obtained the proof on performed repeat control from the Agency from the country of the producer),
- Withdrawal of two medicines batch on the basis of producer's request (sets were withdrawn from market of other countries as well),
- Withdrawal of all batch of the medicine Reductil (in January 2010) which were withdrawn from the EU market by EMA

Information on withdrawal of medicines or specific batch of medicines, are published on the website of the Agency: http://calims.me/ and the Agency directly notifies the healthcare workers.

6. (Ref. to Q 22): Please confirm the year until which import licenses are issued by the Agency on the basis of the registration in EU, USA, Canada, etc.

On the basis of criteria defined in the Law on Medicines, In Montenegro, medicines can be in the market circulation, as it is already mentioned in the answer to the question No. 21 (I), until March 26th 2010. After that date it is envisaged that, only those medicines which possess the market release licence of the Montenegrin Medicine Agency can enter the market, in the manner prescribed by the Law and EU directives.

However, since we have a small number of registered medicines, and since the implementation of this provision of the Law could cause market instability and lack of essential medicines, the Ministry of Health started the amendment procedure of the Law on Medicines, in the pert concerning this provision. The Law on Amendments to the Law on Medicines recommends that within the period of one year from the day of its entering into force, the medicines registered in EU, USA, Canada, Switzerland, Norway and former SFRY, can be in the market of Montenegro, under the condition the medicine producers, through their representatives or agents in Montenegro, have the necessary documentation on quality, safety, and medicine efficiency delivered to the Agency, i.e. they have started the registration procedure with the Agency of Montenegro.

In accordance to Article 20 of the Law on Medicines, in the Montenegrin market, medicines lacking the necessary licence of the agency may be found, if they are necessary for the treatment of a specific number of patients, on the request of a healthcare institution (intervention import).

Adoption of the Law on Amendments to the Law on Medicines is expected for the second quarter of 2010.

7. (Ref. to Q 23): Please specify how many products were tested, and what the results of the tests were.

From the product categories mentioned in the question, in 2008, 89 samples of toys were examined, out of which it is determined 8 of them did not meet health care standards (toys from China). For plush toys and rubber animals, colour inconsistency was determined, and for dolls existence of prohibited softeners was detected.

In 2009, 29 samples were examined, out of which 4 samples did not meet healthcare standards due to existence of Phthalate exceeding allowed limits (PVC toys).

Toy sampling is performed on the basis of risk assessment by the inspector or field information. In 2008 there were more information on toy irregularities in the European market and the neighbouring countries, and consequently we took more samples in 2008 than in 2009.

8. (Ref. to Q 24): Please provide examples.

In 2010, on the basis of the performed tests and obtained results in the previous years, we will perform examinations of products, with special accent on those products that had some irregularities determined before (toys, medicines, etc.).

9. (Ref. to Q 25): Please provide examples.

The media were notified through written announcements for the cases of health risk irregularities of toys.

Information on medicines that do not meet the defined quality standards is published on the website of the Montenegrin Medicine Agency, and the Agency also notified healthcare institutions.

10. (Ref. to Q 26): Please provide examples.

Reasons due to which the competent bodies had practical difficulties in taking samples for testing and the sample testing itself are: insufficient education level of inspectors for assessment of risk of dangerous consumer products; lack of possibility for fast information exchange regarding products that are dangerous to health and safety of consumers, due to lack of Information system; a number of sample testing methods, required by the EU legislation, are in the process of accreditation, and for some methods we are lacking adequate equipment.

In connection with the Consumer Protection Cooperation Regulation (Regulation 2006/2004):

11. (Ref. to Q 29): Please provide the following information:

a) Clearly list the public authorities covering the domain of each of the measures listed in the Annex to the CPC Regulation, i.e. the public authority responsible for the enforcement of each directive/regulation listed in the CPC Annex;

Competent body/bodies:	
1. Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising	Ministry of Economy – Market Inspection, Broadcasting Agency of Montenegro, Ministry of Health – Health-sanitary Inspection, Veterinary Administration - Veterinary Inspection, Phytosanitary Administration - Phytosanitary Inspection, Ministry of Tourism - Tourist Inspection, Ministry for Information Society – Department for Inspection Supervision
2. Council Directive of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises (85/577/EEC)	Ministry of Economy – Market Inspection,

3. Council Directive of 22 December 1986 for the approximation of the laws, regulations and administrative provisions of the Member States concerning consumer credit	Central Bank of Montenegro
4. Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities	Broadcasting Agency of Montenegro, Ministry of Maritime Affairs, Transportation and Telecommunication – Inspection for Electronic Communications,
5. Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours	Ministry of Tourism - Tourist Inspection,
6. Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts	Ministry of Economy – Market Inspection
7. Directive 94/47/EC of the European Parliament and the Council of 26 October 1994 on the protection of purchasers in respect of certain aspects of contracts relating to the purchase of the right to use immovable properties on a timeshare basis	Ministry of Tourism - Tourist Inspection
8. Directive 97/7/EC of the European Parliament and the Council of 20 May 1997 on the protection of consumers in respect of distance contracts	Broadcasting Agency of Montenegro, Ministry of Economy – Market Inspection, Veterinary Administration - Veterinary Inspection, Phytosanitary Administration - Phytosanitary Inspection, Ministry for Information Society – Competent Inspection, Ministry of Maritime Affairs, Transportation and Telecommunication – Inspection for Electronic Communications,
9. Directive 97/55/EC of the European Parliament and the Council of 6 October 1997 amending Directive 84/450/EEC concerning misleading advertising so as to include comparative advertising.	Ministry of Economy – Market Inspection, Broadcasting Agency of Montenegro, Ministry of Health – Health-sanitary Inspection, Veterinary Administration - Veterinary Inspection, Phytosanitary Administration - Phytosanitary Inspection, Ministry of Tourism - Tourist Inspection Ministry for Information Society – Department for Inspection Supervision,
10. Directive 98/6/EC of the European Parliament and the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers	Ministry of Economy – Market Inspection, Ministry of Tourism - Tourist Inspection, Ministry for Information Society – Department for Inspection Supervision, Agency for Electronic Communications and Postal Services, Ministry of Maritime Affairs, Transportation and Telecommunication – Inspection for Electronic Communications,
11. Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees	Ministry of Economy – Market Inspection, Ministry of Health – Health-sanitary Inspection, Veterinary Administration - Veterinary Inspection, Phytosanitary Administration - Phytosanitary Inspection, Ministry of Tourism - Tourist Inspection Ministry for Information Society – Department for Inspection Supervision,
12. Directive 2000/31/EC of the European Parliament and of the Council, of 8 June 2000 - on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market	Ministry for Information Society – Department for Inspection Supervision,
13. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	Ministry of Health – Health-sanitary Inspection, Montenegrin Medicine Agency,
14. Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services	Central Bank of Montenegro Insurance Supervision Agency of Montenegro, Commission for Securities,
15. Regulation (EC) No 261/2004 of the European Parliament and of the Council of 11 February 2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights	Ministry of Maritime Affairs, Transportation and Telecommunication – Competent Inspection,
16. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market	Ministry of Economy – Market Inspection, Broadcasting Agency of Montenegro, Ministry of Health – Health-sanitary Inspection, Veterinary Administration - Veterinary Inspection, Phytosanitary Administration - Phytosanitary Inspection, Ministry of Tourism - Tourist Inspection Ministry for Information Society – Department for Inspection Supervision

b) Explain any shortcomings in their current framework of public authorities and how they expect to enhance their current system.

Shortcomings in the current framework of the Montenegrin competent bodies are related to their capacities, and legal basis, when it comes to particular fields, i.e. directives, which are not fully transferred to the national legislation. Further harmonisation in this direction, will provide more precise division of competencies for the needs of more effective consumer protection. These issues are also addressed in the Strategy of market supervision which will be implemented in the following period. So, as we have already stated, these capacities are going to be further developed.

12. (Ref. to Q 31): Please explain clearly the provisions for consumer protection in the mentioned laws (additional to those already explained) and present them according to the type of measure.

The Law on Internal Market (Official Gazette 49/08): stipulates conditions and manner of trade performance, and the protection from illegal competition in trade. In that sense, the objects in which a person performs trade of goods to consumers must meet required conditions (Article 15 and 31). Distance trade is performed in the stipulated manner within the organised salesmen network (Article 16), and the trade outside of business premises (door-to-door) in the stipulated manner and for the stipulated types of goods (Article 17), and that shall be, during this year, closely regulated through bylaw (Article 34, Paragraph 4). It is also obligatory for a salesman to clearly indicate working time and to observe it (Article 36). A salesman has to have the licence for goods s/he releases into circulation, and goods have to meet prescribed conditions, i.e. to have declaration, labels, and accompanying documents, etc. (Article 32). Additionally, the provisions of this Law protect consumers from illegal competition activities which are prohibited by this Law (Article 38). Illegal competition shall be considered any activity of a salesman which, contrary to good business practices, cause or can cause harm to a consumer (Article 39), and especially: advertising, announcing, or offering of goods by indicating data or using terminology which is or can be misleading; hiding of goods disadvantages, or any other type or consumers misleading; coaxing of consumers or service users by offering or promising awards or any other benefit or advantage which are more significantly more valuable than the usual commercial award (Article 40).

For the violation of the abovementioned obligations, the Law defines misdemeanours (Article 43 and 44), for which the fine for a salesman is in the amount of thirtyfold up to fiftyfold amount of the minimal salary in Montenegro, and for certain misdemeanours from fiftyfold up to three hundredfold amount. For these misdemeanours, the fine is also stipulated for a responsible person within the legal entity and for a physical entity, in the amount of threefold up to fifteen-fold, and tenfold up twentyfold amount of the minimal salary in Montenegro respectively. Fine can be accompanied by the possibility of issuing the protective measure of seizure of goods constituting the misdemeanour and the protective measures of prohibition of trade activities from three months up to one year (Article 43)

Additionally, for smaller misdemeanours, a Market Inspector has the competence to issue on the spot fine, for an entrepreneur from twofold to fivefold mount of the minimal salary in Montenegro, and for a responsible person within the legal entity from one up to threefold amount (Article 45). The Inspector may take other actions against a salesman, which are stipulated by this Law and the Law on Inspection Supervision.

Law on Food Safety (Official Gazette 14/07): stipulates that food and food for animals, during the production and market release, has to be declared and labelled. Data from the declaration and label have to match data specified in manufacturer's specification and requirements defined by the Law and regulations adopted on the basis of this Law. Declaration shall not contain data on curative properties of food for people and food for animals.

Declaration, i.e. data on the declaration for foodstuffs and food for animals released into market shall be written in the official use language in Montenegro.

Advertising and presentation of foodstuffs and food for animals, design, environment and information on foodstuffs and animal food which are available through print and other media shall not be misleading for a consumer of animal holder. Foodstuffs and food for animals' advertisements and presentations shall not contain data on curative properties of food.

According to the Law a competent body can issue fine to a subject of supervision if foodstuffs and food for animals in production or market are neither declared nor properly labelled, and if advertising and presentation of foodstuffs and food for animals are misleading for a consumer and contain data on curative properties of food (Article 82). This article defines the fine from hundredfold to three hundredfold amount of the minimal salary in Montenegro. Competent bodies supervising the implementation of the Law are: Sanitary Inspection, Veterinary Inspection and Phytosanitary Inspection.

Law on Medicines (Official Gazette 80/04 and Official Gazette 18/08): stipulates, apart from other issues, the rules related to declarations and labels, advertising and medicine pricing.

Labelling of medicines is defined in Article 82 and 83 of the Law, instruction for the patient – beneficiary in Article 84, labelling of outer and internal package of a medicine and the contents of the instructions for patients enclosed to the package Montenegrin Medicine Agency (Article 85). The same Article defines contents and the manner of labelling the outer and internal package of a medicine as well contents of the instructions for patients are in more details determined by the Ministry i.e. ministry competent for the veterinary medicine affairs regarding veterinary medicines.

Moreover, the Law stipulates the rules of advertising and the prohibition of advertising of medicines (Article 91 - 96) such as: Medicines that are dispensed without prescription can be advertised in the media and in other ways, i.e. the information about these medicines can be given only in compliance with the summary of the basic characteristics of the medicine and that is a constituent part of marketing authorization. Advertising has to be objective and it may not be misleading. It is prohibited to advertise medicines to children through direct addressing to children whose treatment the medicines are intended for. Manufacturers of medicines, representatives of manufacturers and legal entities that trade in medicines shall not offer financial, material or other benefit neither to the persons prescribing or dispensing medicines nor to the members of their families. It is prohibited to advertise to general public the medicines that are prescription-only or that contain psychotropic substances or narcotics. It is prohibited to advertise the medicines without marketing authorization or whose marketing authorization ceased to be valid.

The Ministry competent for healthcare affairs, there is the Department for Healthcare Sanitary Inspection Affairs, performing inspection supervision, apart from other activities, over announcement of medicines in accordance to the Law and prohibits circulation, i.e. prohibits release into the market for those medicines which do not meet the defined standards of medicine quality, safety and efficiency.

The Montenegrin Medicine Agency shall be competent for taking measures for immediate withdrawal of medicines and batch of medicines in particular cases, and shall notify the public, within the period of 24 hours, regarding its measure (Order of prohibition, stopping of marketing of medicines and batch of medicines and withdrawal from circulation). Medicines for which the expiry date has passed, or which are determined to be incorrect in terms of the regulated quality, as well as other medicines the marketing of which is prohibited or which are withdrawn from the Market, have to be destroyed in accordance with manufacturer documentation on basis of which the marketing authorization was issued (Article 76).

On the basis of the Law the Government adopted the Decree on Criteria for the formation of maximum medicine prices (Official Gazette 50/07) defining the criteria for the formation of maximum medicine prices for wholesale and retail trade. The Ministry competent for market affairs, through the Market Inspection, shall perform inspection supervision over prices and released medicines.

Violation of the stipulated obligations is defined as misdemeanour (Article 101), if: determines the prices of medicines contrary to the provisions; does not destroy medicines for which the expiry date has passed or it is determined to be incorrect in terms of the regulated quality, as well as other medicines the marketing of which is prohibited or which are withdrawn from the market; advertises to the professional community a prescription-only medicine contrary to the provisions of Article 92; advertises medicines that are dispensed without prescription contrary to the provisions of Article 93 of this Law; offers financial, material or other benefit to the persons prescribing or dispensing medicines as well as to the members of their families; advertises to general public the medicines that are a prescription-only or that contain psychotropic substances or narcotics or medicines without marketing authorization or whose marketing authorization ceased to be valid. For the violations, a fine shall be paid by a legal entity, in the amount of hundredfold to two hundredfold amount of the minimum labour price in Montenegro, and for the responsible person within the legal person from tenfold to twentyfold amount of the minimum labour price.

Article 103 defines a fine in the amount of fortyfold to hundredfold minimum labour price in Montenegro shall be imposed on a legal entity if it: markets a medicine which is not labelled in the Montenegrin language according to the marketing authorization and the summary of basic characteristics of the medicine; markets a medicine labelled contrary to the provision of the Article 83 of this Law; instruction for the patient is not in accordance with the approved short summary of the basic characteristics of the medicine or it is not written in the Montenegrin language, and in communities with significant number of members of national minorities and other minor national communities in their language and alphabet, and if it is not prepared in the manner which is understandable to the patients. For the above-mentioned violations a fine in the amount of four to ten amount of minimum labour price in Montenegro shall also be imposed on the responsible person in the legal entity.

The Law On Genetically Modified Organisms (Official Gazette 22/08), stipulates rules regarding labelling of packages and accompanying documentations of GMOs or regarding products containing or originating from GMOs (Article 48), and advertising rules for these products (Article 51). In the case of violation of these rules, competent bodies shall take stipulated measures. (Ministry of Health – Sanitary Inspection, Veterinary Administration – Veterinary Inspection, Phytosanitary Administration – Phytosanitary Inspection, and Environment Protection Agency – Environmental Inspection).

Law on Tourism (Official Gazette 32/02, 41/02, 45/02, 38/03 and 31/05): stipulates rules on pricing, advertising, including promotional sale. In Article 66 Paragraph 1 Item 5 (provision of hospitality service), a caterer shall “clearly display price list for services offered in a manner available to guests and conform to the displayed and published prices, and in the provision of the accommodation services include in the price list the amount of dwelling tax”. The same provision (Item 6) the caterer shall “provide adequate number of copies of price lists available to guests“, while Item 7 of the Article defines the obligation of bill provision to guests for each hospitality service offered.

For the violation of the abovementioned obligations the Law stipulates, in Article 118, Paragraph 1, Item 2 and Paragraph 2 a fine for a caterer from tenfold up to sixtyfold amount of the minimum salary in Montenegro. In addition to the fine, the caterer shall be issued the protective measure of the prohibition of catering activity in the duration of one year, if it is established that the caterer, during the past two years, was punished by valid decision for the abovementioned violation (Article 119, the Law on Tourism).

In addition to this, the Law also stipulates the special competence of a tourism inspector who can issue an order to the provider of catering and tourist services to return the (overpriced part) difference to a consumer and without delay submit the request for the institution of misdemeanour procedure (Article 110, the Law on Tourism).

Law on Limiting the Use of Tobacco Products (Official Gazette 52/04) – defines rules for labelling of tobacco products, and rules for advertising and promotional sale as well. So, in other to protect environment and health, the Law stipulates the measures for the reduction and limitation of tobacco products (placement of obligatory labels, prohibition of advertising, etc.).

Competent bodies for the control of implementation of the Law are: the Market Inspection and Sanitary Inspection.

For the violation of the abovementioned obligations, the Law stipulates that a fine shall be issued from twentyfold to thirtyfold amount of the minimal salary in Montenegro. In addition to the fine, the protective measure of seizure of tobacco products shall be taken.

Law on Tobacco (Official Gazette 48/08, 76/08) stipulates a salesman who, sales tobacco products, has to conform to retail prices s/he had published in the Official Gazette of Montenegro. For the violation of the abovementioned rules, i.e. if the prices are different from the published ones, a salesman shall pay the fine from two hundredfold to three hundredfold amount of the minimum labour price in Montenegro. Competent body for the control of implementation of the Law is the Ministry of Economy – the Market Inspection.

Law on Broadcasting (Official Gazette 51/02, 62/02, 56/04 ...) stipulates rules on advertising, including products recommendation, and measures in the case of rule violation. The content of the Law regarding the elements of from this question is presented in the answer to the main question No. 28.

13. (Ref. to Q 32): In the answer to Question 32 examples of enforcement activities carried out have been provided. However, we would also like Montenegro to clearly list the specific powers of each public authority to bring about the cessation of an infringement of laws protecting the economic interests of consumers, including in cross-border cases. For example:

a) Can the public authority impose a fine?

Apart from the measures taken by the competent bodies, with a view to protecting consumers' economic interests (given in the answer to the main question no. 32), the bodies, regarding the issuance of fines, have the following authorities:

Inspections may issue an on-the-spot fine to a salesman (mandate fine), in accordance to Article 135 of the Law on Consumer Protection, and in accordance to other laws containing provisions on consumers' economic interests, for which there is a possibility for issuance of on-the-spot fine.

The Broadcasting Agency may issue a fine in accordance to Article 49 of the Law on Broadcasting, upon the broadcaster:

- in spite of the warning violates the obligation prescribed by this Law or by the regulation of the Agency based on this Law.
- violates the obligations related to the terms and quotas for the broadcasting of advertisements, prescribed by the Agency.

All of the decisions on penalty measures to the broadcasters, the Agency shall adopt after the conducted procedure, during which the broadcaster has the right to express opinion, and publishes them in the Bulletin of the Agency and in other manners defined by the Agency Statute and this Law.

The Central Bank does not have authorisation to issue fine to banks for violations. In the case there is a doubt a bank has violated provisions of the Law on Banks, the Central Bank starts misdemeanour procedure, before a competent body, against the bank and a responsible person in the bank CB.

The Law on Banks, authorises the Central Bank, if the conditions are met, to take measures against a bank. The measures are in practice similar a fine. Namely, if the measures, towards a bank, are taken is the form of the decision, the very decision obliges the bank to pay certain funds to the Deposit Protection Fund, in the amount of 0.1% up to 1% of the bank's funds. This decision may contain the amount which is to be paid by the Director Board members and an executive bank

director, and the amount is in the range between twofold up to tenfold amount of an average employees' salary in the bank.

The Agency for Electronic Communications, Insurance Supervision Agency of Montenegro and Commission for Securities do not have an authorisation to issue a fine.

However, all of these bodies are authorised, if they determine the consumers' economic rights are violated, and that violation is punishable, to institute a misdemeanour procedure before the competent body for misdemeanours, which can issue the fine.

Competent body for misdemeanours leads the procedure in accordance to the Law on Misdemeanours and issues fines in accordance to the material law stipulating the particular misdemeanour.

b) Can it obtain an injunction?

The bodies are not authorised to start a procedure before the competent court, in order to protect consumers' rights, in the sense of Directive on Court Injunction, and consequently they can not obtain injunction. Authorisation for filing a complaint in order to protect collective consumers' interest, before a competent court, in accordance to the Law on Consumer Protection, is in the hands of consumers' organisations.

However, as it is already mentioned, all of these bodies are authorised, if they determine the consumers' economic rights are violated, and that violation is punishable, to institute a misdemeanour procedure before the competent body for misdemeanours.

c) Can it remove a trader's licence?

Inspections cannot revoke licence of a salesman.
However, in the stipulated cases, they can implement the temporarily measure and prohibit the performance of activities, and prohibit marketing, until an irregularity is removed.

The Insurance Supervision Agency of Montenegro, in accordance to Article 144, Paragraph 1 and Item 4 of the Law on Insurance, may adopt a decision to revoke licence to an insurance company regarding the performance of some or all of the activities, if the company violates the rights of an insurance holder, insurance beneficiary or if the company does not pay for damages or fulfil other responsibilities.

The Commission for Securities may, in accordance to the Law on Securities and bylaws, revoke licence to a subject, operating in the market for securities, if it violated the provisions related to the protection of economic consumers' rights. In the case of violation, the Commission has the authorisation to take measures towards the controlled subject in order to remove the irregularities. In the case the Commission's measures are not observed the Commission takes defined measures.

The Central Bank may, in accordance to Article 116 of the Law on Banks, revoke work licence of a bank, in the case of violation of this Law and other laws including there provisions on client protection. Additionally, the Central Bank is competent to take the following measures as well:

- send written warning to a bank related to determined irregularities and order bank to remove these irregularities in a defined period of time;
- conclude written agreement on the removal of the determined irregularities;
- order to a bank measures to remove determined irregularities;
- introduce temporary measure in a bank.

Which measure will be taken depends on the number and gravity of determined irregularities, previous violations by the bank, readiness of the bank bodies to remove irregularities and level of impact of determined irregularities on financial discipline, safety and stability of banking system.

The Agency for Electronic Communications and Postal Services, in accordance to the Law on Electronic Communications, may revoke an approval for use of radio frequency and approval for use of numeration and/or addresses:

Revocation of Approval

Article 81 of the Law on Electronic Communications (Official Gazette 50/08) defines the cases where the Agency for Electronic Communications and Postal Services may revoke an approval for use of radio frequency either ex officio, at the suggestion of the party to whom that Approval has been issued, or upon request of the State Prosecutor.

The Agency shall be obliged to initiate, ex officio, the procedure for revocation of a radio frequency approval for use of broadcasting frequencies if requested to do so by the Regulatory Body for Program Contents, according to the Law.

The Agency may revoke a radio frequency approval at the request of the holder if she/he has met all obligations according to this Law and terms and conditions of the radio frequency approval.

The Agency shall revoke a radio frequency approval ex officio if it determines that:

- the request for the radio frequency approval contained false information;
- Holder of Approval does not obey the prescribed conditions pursuant to this Law or conditions from in the radio frequency approval
- the deficiencies that the Agency issued the order to be removed, have not been removed within the stipulated time interval;
- the fees for use of radio frequencies, were not paid irrespective of a notice previously issued by the Agency on outstanding obligations
- It is not possible to otherwise avoid harmful interference.

Revocation of Approval for Use of Numeration and/or Addresses

Article 96 of the Law defines the cases where the Agency for Electronic Communications and Postal services may revoke an approval for use of numeration and/or addresses upon request of the holder thereof and ex officio if:

- the holder of the approval for use of numerations and/or addresses does not meet the conditions laid down in this Law,
- the annual fee for the use of numerations and/or addresses was not paid in due time;
- the holder of the approval for use of numerations and/or addresses has not began to use the assigned numerations and/or addresses within two years from the date of the assignment
- the numerations and/or addresses are not used in accordance with Article 93 Paragraph 1
- Item 2 and 8 of this Law
- that holder of Approval for use of numerations and/or addresses has submitted request for revocation of Approval.
- that significant changes in the Plan on Numeration or Plan on Addresses occurred and it is not possible to change the Approval, due to non availability of adequate resource.

The Agency shall submit the decision with an explanation of revoking of assigned numerations and/or addresses.

In cases where the revocation is a result of unpaid annual fee to the Agency, the term for revocation may not be shorter than thirty 30 days from the date of receiving the decision

Where the right to use numerations and/or addresses is revoked upon the request of the holder, the term for revocation shall not be shorter than sixty days from the date of receiving the decision.

The revocation of the numerations and/or addresses shall be conducted by way of disconnection from traffic by the operators of public communications networks, upon a decision obtained from the Agency.

d) Does the public authority have to go to Court?

In the application of the abovementioned competencies, in order to prevent the violation of the Law protecting economic consumers' interests, these bodies do not have to before court.

We want to emphasise, an inspection, if it determines there is a violation of the Law, which is not punishable by fine, have to start misdemeanour procedure before the competent body, and if the violation is punishable by on-the-spot fine, it can issue the fine and in that context there is no misdemeanour procedure. /more in the answers under a) and b)/. Additionally, other bodies are also authorised to instigate the misdemeanour procedure before a competent body if they determine the violation of consumers' economic interests.

Note: In order to clarify and correct the given answer to the main question no. 32 (and 28):

In the previous answers to the main questions no. 28 and 32 it is stated that a Bank Ombudsman is appointed, however, we adopted the Decision on Bank Ombudsman (Official Gazette 15/09), but the appointment procedure is not yet finished.

Rights and obligations of the Bank Ombudsman, related to client protection of banks, microcredit financial institutions and credit unions, are defined by Article 92 of the Law on Banks. A client who is not satisfied with an act, activity or omission of these subjects may refer to the Bank Ombudsman, who is an independent subject, and who, in the out of court procedures participates in finding solution between clients and banks, i.e. microcredit financial institutions and credit unions.

The Bank Ombudsman has the following competencies:

1) Considers clients' complaints and recommends to the parties in dispute to settle it or finish in some other way;
2) Gives recommendations to banks, microcredit financial institutions and credit unions in order to improve relations to clients;
3) Give advice to clients, related to the dispute procedure;
4) Performs other activities which support the protection of client's rights.

Bank client may address the Bank Ombudsman only if s/he had already used up all the legal possibilities, related to the protection of his/her rights before a bank, microcredit financial institution and credit union. The procedure before the Bank Ombudsman cannot prevent a client to start a procedure, related to the same subject, before the competent court. The Bank Ombudsman is not yet appointed.

14. (Ref. to Q 33): Please provide also information on enforcement of consumers' legislation in relation to financial markets and insurance.

<u>The Commission for Securities</u>

The Commission, through continuous direct or indirect control, controls the operation of subjects. authorised participants in the securities' market (brokers i dealers), custody banks and other banks in the pert related to the performance of activities related to securities and fulfilment of responsibilities defined by the Law on Securities and the regulations adopted on the basis of the Law.

Responsibilities of these subjects for the part related to the provisions on consumer protection include:

- responsibilities of an authorised participant regarding the provision of information to a client on transaction risks, advantages and disadvantages, responsibility of the authorised participant to make him/herself familiar with client's financial state, his experience in investing and information necessary, so that a client is able to reach appropriate decisions regarding investments;
- responsibilities of notifying general business conditions, i.e. the authorised participant has to provide a client with necessary information of the participant's identity and address, and identity and status of employees and other relevant persons who the client has contacts with.
- control of the manner of the authorised participant actions regarding consumer's complaints, which includes timely actions to the client's objections and legal validity of such actions, and the existence of efficient internal procedures in order to react to client's complaints.

In the case of violation, the Commission is competent to take necessary measures towards the controlled entity in order to remove determined irregularities. Violation of the order to remove determined irregularities gives the Commission authorisation to take measures from their competency.

The Commission for Securities, up to this date, did not determine any irregularity with the subjects providing services of securities trading in the market regarding the implementation of provisions regulating actions following a client's complaint.

The Insurance Supervision Agency of Montenegro

The Insurance Supervision Agency of Montenegro performs supervision over the work of subjects from the Law on Insurance (Official Gazette 78/06 and 19/07), where are: insurance companies, reinsurance, mediation, representation in insurance, and for all physical entities dealing with insurance in the form of business and employment in some of the abovementioned companies. Additionally, the Agency controls the implementation of procedures regarding market behaviour, especially procedures regarding submission, processing and liquidation of compensation requests.

Control of the Insurance Supervision Agency, encompasses technical capabilities of a subject of supervision, which implies the possession of appropriate premises for the performance of all activities, as a precondition for adequate functioning, reception of clients and protection of their rights.

The Agency does not perform target controls of the respect of provisions of the Law on Consumer Protection, but if it receives a complaint, it can perform control and take supervision measures to any company which is not performing their activities in accordance to all regulations from this field. This is also related to the obligations towards consumers stipulated by the Law on Consumer Protection, which are applicable to the operation of insurance companies.

In accordance to the Law on Insurance, the Agency shall act upon the reception of beneficiaries'' complaints, decisions are adopted by the Agency Board, and the procedure is closely defined in the Insurance Supervision Agency Statute (Official Gazette 30/08). The Statute defines a beneficiary may submit their complaint to the Agency, if they had already submitted the complaint to a insurance company and s/he was not satisfied by the response, the complaint was rejected or if the insurance company did not reach decision on complaint within the period of 30 day for the day or valid complaint reception. The Agency Board, in order to assess validity of the complaint, may seek from the insurance company all the necessary documents, and additional information may be sought from other state bodies and institutions.

In accordance to Article 130, Paragraph 1 and Item 6 and 7 of the Law, the regulatory body shall order to a insurance company to remove irregularities, if the body determines the company acts against the Law, other regulations and general acts which stipulate insurance company operations,

and if the company acts towards policyholders and other insurance beneficiaries, against the rules of insurance profession, good business practice and business ethics

Neither the rights protection procedure through the Insurance Supervision Agency, nor contact to other bodies, shall exclude the right on court protection as the final mean for the provision of policyholder rights.

Since we have started with preparation activities to amend Law on Insurance, we expect the provisions related to customer protection will be stricter and closely define which will lead to better transparency in market behaviour and better protection of all insurance beneficiaries.

15. Concerning Directive 2008/122/EC on the protection of consumers in respect of certain aspects of timeshare, long-term holiday product, resale and exchange contracts: Please inform when Montenegro plans to adopt the corresponding transposition measure.

Directive 2008/122/EC shall be transferred into the national legislation through amendments to the Law on Customer Protection. It will start in the second half of 2010, and finish in 2011.

16. Concerning the Consumer Credit Directive (2008/48/EC), the Distance Marketing of Financial Services Directive (2002/65/EC) and the Injunctions Directive (2009/22/EC): From the information provided it appears that the above Directives have not yet been transposed. It would be useful to have a timetable and planning of future transposition and implementation.

Directive on credit agreements for consumers (2008/48/EC)

In the answers to the questions no. 27 and 28 we have already presented the regulations containing provisions on agreements, and given data regarding the fact that we finished the analysis of national legislation in the field of agreements for consumers regarding the EU legislation. On the basis of the analysis the need for harmonisation of regulations with Directive 2008/48/EC is recognised. Since this is a new Directive, The Central Bank and The Ministry of Economy as the competent Ministry for consumer protection, are going to reconsider earlier opinion regarding the scope and manner of further harmonisation. In that direction, we will take activities within the 2009 IPA Project (component consumer protection), and the start of implementation is expected for the first half of this year. After the selection of optimal solution we will start harmonisation of national legislation with the Directive, within the deadline that is going to be defined in the new National Programme for Integration of Montenegro into the EU.

The Directive on Distance Marketing of Consumer Financial Services (2002/65/EC)

The Directive on Consumer Financial Services is mostly implemented through documents regulating operations with securities in Montenegro. With a view to implementing of the Directive, the Commission for Securities adopted the Rules on manner of operation of authorised participants in the securities market (Official Gazette 78/09 and 87/09) which are related to:

- information delivered to clients prior to the conclusion of contract regarding the performance of activities with securities. This include information regarding its identity and address, and identity and status of employees and other relevant persons that have contacts with a client (including information on risks) which are necessary in order for the client to be able to reach an appropriate decision regarding investments
- use of distance communication means for conclusion of contracts regarding the performance of activities with securities, which is enabled by this rules.

The Directive (2002/65/EC) will be fully implemented through the Law on Securities by the end 2012, in accordance to the National Programme for Integration. This Directive is not specially

included into the NPI due to the fact is partially related to performance of activities of authorised participants in the market who perform affairs with securities.

The existing Law on Insurance (Official Gazette 78/06 and 19/07) did not include the Directive (2002/65/EC), and the deadline for its inclusion is not yet defined by the Internal Plan of the Insurance Supervision Agency of Montenegro. Certainly, the Agency, shall take all the necessary measures in order to finish harmonisation in the following period.

In the answers to the questions no. 27 and 28 we have already presented the regulations containing provisions on distance marketing, and given data regarding the fact that we finished the analysis of national legislation in the field of distance marketing (together with the analysis from the field of consumer financial services) regarding the EU legislation. On the basis of the analysis the need for harmonisation of regulations with Directive 2002/65/EC is recognised. Since this is the Directive, related to the field of financial services, it is necessary to, apart from already mentioned, start amending several laws related to this filed. The Ministry of Economy as the competent Ministry for consumer protection, together with competent bodies and institution for financial services, are going to take activities within the 2009 IPA Project (mentioned in the answer to the previous Directive), and define regulation harmonisation plan regarding the Directive, within the deadline that is going to be defined in the new National Programme for Integration.

Directive on injunctions for the protection of consumers' interests (2009/22/EC)

Directive on injunctions shall be transposed into national legislation through amendments of the Law on Consumer Protection, and the preparation will start in the second half of 2010 and finish 2011.

B. Product safety-related measures:

17. (Ref. to Q 3(b)): Please provide (translated into English if available) the Law on Inspection Control (Official Gazette of the Republic of Montenegro No. 39/2003) and the Decree on Joint Inspection Control (Official Gazette of the Republic of Montenegro No. 48/03).

The Law on Inspection Control (Official Gazette 39/03 and Official Gazette 76/09) and the Decree on Joint Inspection Control (Official Gazette 48/03) are attached to this document and translated into English.

18. (Ref. to Q 19(c)): Please provide (translated into English if available) an example of an annual market surveillance plan (for example, for 2010) and an example of a report on the monitoring of accomplished activities in the area of consumer product safety (for example, an annual report for 2008 or 2009). If no such formal documents are established, please indicate so and provide information on whether any such documents are planned to be drafted in future).

Attached to this document are 2008 Work Programme and 2009 Market Inspection Report on Work, both translated into English.

The Market Inspection plans its work at annual level, starting from defined competencies, market situation and other relevant circumstances, in order to achieve market regularity through efficient inspection supervision. Implementation of its Agenda is enhanced by dynamic short-term plane (monthly), which are used to plan supervision over particular fields and product types, depending on the increase in trade of particular products during particular periods. For instance: the control of construction products trade during the period when there is an increase in building new objects, or

stricter controls of discount notifications during the period of seasonal discounts. Additionally, priority is set towards consumer complaint and initiatives of other entities. Since the end of 2008 and the beginning of 2009 were used for the creation of the Market Supervision Strategy, the Agenda for 2009 was not adopted. However, inspection supervision methods, rules of cooperation with other subjects, manner of notification and other elements that are of vital importance for efficient supervision from the Annual Work Programme, attached to this document, are the main principles on the basis of which we planned monthly activities in 2009. In this year, the basis for planning the work of the Market Inspection is the Market Supervision Strategy of Montenegro.

Monthly planning and monthly performance analysis are discussed on the meetings, held by a Chief Market Inspector regularly every month, together with coordinators of territorial units. The following topics are discussed:

- Analysis of conclusions from the previous meeting,
- Previous month report discussion,
- Agenda for the next month,
- Other issues.

Monthly work reports are regularly submitted on the defined forms and according to defined rules:

- Inspectors submit monthly work reports to the territorial units coordinators until the fifth of the month, for the previous month;
- Coordinators submit territorial unit work reports (joint reports of inspectors for these territorial units) to the Chief Inspector until the tenth of the month, for the previous month;
- The Chief Inspector submits inspection work report to the Ministry of Economy until the fifteenth of the month for the previous month. The Chief Inspector additionally submits six month reports and annual reports as well.

Apart from the abovementioned frequencies, reports, if necessary, can be submitted more often.

19. (Ref. to Q 19(e)): Please indicate the number of testing facilities used within the performance of risk assessment in respect of individual products suspected to pose risks to health and safety consumers. Also, please indicate how many of such testing facilities possess private and public status.

In Montenegro, there are 8 product testing bodies (which are accredited), with a view to assessing risk to health and consumer protection, out of which 5 (four laboratories and one control organisation) have private status, and 3 (two laboratories and one for standardisation) have public status.

20. (Ref. to Q 19(f)): Please indicate by which means the information on products posing risks to health and safety of consumers is channelled to the public? If it is done through a dedicated website, please indicate its web address. Also, please provide certain examples of such communications to the public (identification details of dangerous products described in these communications can be deleted).

Announcement of Information regarding dangerous products is the responsibility of an inspection body which determined such product is in the market. The responsibility is stipulated in the Law on General Product Safety and the Law on Consumer Protection /more details in the answer to the main question no. 20 g) and 19 f)/, and the Law on Inspection Supervision as well (Article 8).

So, apart from administrative and other measures which are obligatory for them, inspection bodies are obliged to notify the public. This is done by an announcement through print and electronic media, and if the body has a website, through the website as well.

Information for medicines, which do not meet quality standards, is published on the website of the Montenegrin Medicine Agency (www.calims.me).

During this year, we plan to create the Market Inspection website, where, apart from other information, there will be information on products which represent danger to the health and safety of consumers.

During 2010 Phytosanitary Inspection will get its website, where it will be able to announce, in the national language (languages) all the information regarding dangerous products.

Example: In 2009 the Market Inspection, announced information in media (print and electronic), regarding cases where the control (through sample analysis of competent bodies) of oil-derived liquid fuel showed it did not meet the required standards.

(http://www.dan.co.me/index970.php?nivo=3&rubrika=Ekonomija&clanak=212009&najdatum=2009-12-12&datum=2009-12-14)

21. (Ref. to Q 20(d)): Please indicate the number of administrative measures taken against products posing (i) serious and (ii) non-serious risk to health and safety of consumers in the years 2007, 2008 and 2009, or of any of these years, if data for each of these years are not available.

Administrative measures, taken by the inspection bodies, regarding products representing risk to health and safety of consumers are stipulated by the Law on General Product Safety, the Law on Consumer Protection, the Law on Inspection Supervision, other material laws and technical regulations (sectoral).

Further harmonisation of regulations, especially by adoption of technical regulations, which will transfer the directives into the national legislation, and establishment data exchange system regarding unsafe products in the market, we will be able to implement even more European standards for consumer protection on the field of product safety. Contribution to this goal will be provided by the further implementation of the Market Supervision Strategy, in accordance to which the market supervision will be coordinated.

Inspection bodies performing market supervision do not have information systems, and due to this fact, they are unable to monitor data on measures taken individually by products. From these reasons, we will provide data by individual inspections, regarding the total number of taken measures related to the supervision of products in the market from the field of product safety:

Market Inspection**:**

Market Inspection in 2009, regarding product safety in the market, performed administrative control of products related to: proof of origin of imported goods, labelling and declaration of marketed products, accompanying product documents (certificates, technical instructions, instructions for use, warranties …). Additionally, through the control of oil-derived liquid fuel in the market, the Inspection, in 26 cases took 78 samples, in order to check if they are in accordance to the stipulated standards.

In product safety control, in 2009, the Inspection found 9.968 irregularities related to the violation of provisions of the Law on Consumer Protection and technical regulations. For the removal of these irregularities, particular administrative measures and activities were taken. In that sense, the Inspection took notification measures and adopted decisions on the removal of these irregularities, and the deadlines were given. In 2.653 cases inspectors prohibited marketing of goods due to: irregular declaration, lack of accompanying documents, expired best before date or violation of prescribed standards. For the removal of irregularities, deadlines were give, and for the cases where the expiry date passed (42 cases), permanent marketing prohibition measures were taken. In the cases where it is established the samples (liquid fuel) did not meet the required standards (six samples), if a subject of supervision demanded, the second sample analysis, a temporary

measure of marketing prohibition was taken, and simultaneously the second sample was sent to the competent institution for analysis. In the cases where the subject of supervision accepted the first sample analysis result, or the second sample analysis results showed irregularities, the inspectors permanently prohibited trade. Other competent bodies (Environmental Protection Agency) were notified in order to take measures from their competencies, and the public was also notified through the media.

Apart from the abovementioned measures, taken in the cases of irregularities related to the product safety in the market, additional measures were taken, including institution of misdemeanour procedure before competent bodies or issuance of on-the-sport fines (mandate fine) etc. Precise data related to the number of measures, except for the presented ones, are not available, since they belong to the data group of measures for other taken for other irregularities.

In 2008, the Market Inspection, regarding the product safety, found 9.931 irregularities, which violated the Law provisions on labelling and declaring, accompanying documents and other irregularities. Apart from other administrative measures and actions, taken in this context, there were 2.707 cases of prohibition of product release into market, out of which 2.645 cases the prohibition was temporary and in 62, the prohibition was permanent. Reasons for these measures are usually connected to incorrect declaration (no declaration, incomplete declaration, declaration not translated into Montenegrin), lack of required documents, or lack of documents translated into Montenegrin. For the removal of these irregularities and prevention of violation of the mentioned provisions, we took necessary administrative measures and actions and misdemeanour procedures were instigated against responsible persons.

In 2007, the Market Inspection, regarding the product safety, found 6.953 irregularities, and there were 3.973 cases of prohibition of product release into market, out of which 3.405 cases the prohibition was temporary and in 568, the prohibition was permanent. It should be mentioned the Inspection in this year also performed controls of foodstuffs regarding declarations. Measures were usually taken due to incorrect declarations (no declaration, incomplete declaration, declaration not translated into Montenegrin), lack of required documents, or lack of documents translated into Montenegrin. For the removal of these irregularities and prevention of violation of the mentioned provisions, we took necessary administrative measures and actions and misdemeanour procedures were instigated against responsible persons.

Sanitary Inspection:

Sanitary Inspection did not keep special records on inspection supervision for non-food products in the internal market (cosmetics, toys, and general use objects). The record has been established since the beginning of 2010.

Environmental Inspection:

Environmental Inspection in 2009 performed 80 inspection controls of entities performing radiation activities. It issued 42 decisions related to taking particular measures and actions in order to remove determined irregularities, measurement of the level of individual external exposure of professionally exposed people, performance of medical examinations of professionally exposed people in radiation zone, dosimetric controls, controls of working environment measuring in order to impellent control for sources of ionising radiation. The Inspection submitted 6 requests for the instigation of misdemeanour procedure on the basis of the Law on Protection from Ionising Radiation and Radiation Safety. Two decisions were adopted by which it was ordered to remove from the market chemical substances with expired best before date.

Metrological Inspection:

Metrological Inspection, started its work in December, and in that month it performed 14 inspection supervisions (precautionary action according to the Market Supervision Strategy of Montenegro) and adopted 6 decisions related to the implementation of certain measures and activities in order to remove established irregularities.

II. Public Health

22. (Ref. to Q 36): Could you please provide data on maternal mortality?

Maternal mortality: According to the Agency for Statistics of Montenegro, in 2001, two women died after suffering consequences of pregnancy and giving birth (0.22/1000 of liveborns, i.e. 22.62/100.000 of liveborns), while in 2002 there were no such cases, until 2007, when we registered one death due to the abovementioned reasons (0.12/1000 of liveborns, i.e. 12.76/100.000 of liveborns). In 2008, according to the same source, there were no registered cases of maternal mortality due to pregnancy, giving birth and puerperium.

23. (Ref. to Q 37): Please give more details on intended changes, and provide information on the Ministry of Health's responsibility in the area of blood and blood products.

In the answers to the questions no. 52 and 53 from Chapter 28 of the Questionnaire, we stated the level of harmonisation with the EU laws and regulations, current situation of blood transfusion service together with identified disadvantages, and we gave a model of new organisation planned according to strategic documents. In accordance to this:

- The Government of Montenegro adopted the Decision on the establishment of the Blood Transfusion Agency of Montenegro (Official Gazette 80/09 from 07th December 2009) which established the Blood Transfusion Agency of Montenegro, as a public healthcare institution. The Agency is located in Podgorica. The Agency shall perform its activities in accordance to the law. The bodies of the Agency are: Director and Director Board, appointed by the Government, on the recommendation of the Ministry of Health. WE are currently registering and making general acts which will, apart from other things, define the number and the type of necessary human resources for the performance of Agency activities, which is not disrupting daily activities of the former Centre for Transfusion within the Clinical Centre of Montenegro.
- The Law on Provision of Blood (Official Gazette 11/07 from 13th December 2007), stipulates the conditions and the standard of quality, safety and supervision over the collection, testing, keeping, distribution, using of human blood and blood components. Collection, testing, keeping, distribution, using of human blood and blood components shall be performed in accordance to good producers' practice, the EU directives and WHO recommendations, and other regulations in this field as well. Activities form this field shall be performed by the provision of a sufficient number of unpaid volunteers for blood transfusion in accordance to the recommendations of the EU and WHO. These activities shall be performed by the Blood Transfusion Agency of Montenegro, under the supervision of the Ministry of Health. The Agency shall perform its activities through its organisational units in healthcare institutions as well, if they, for the treatment purposes, use blood, in accordance to the regulations of the Agency.
- Inspection supervision over the application of the Law on Provision of Blood and other regulations from the healthcare field shall be performed by the Ministry of Health through the work of the Healthcare Protection Sector. Inspection supervision is directly performed by the Healthcare Inspector in accordance to the Law on Healthcare Inspection. In the performance of inspection supervision the Healthcare inspector has responsibilities and obligations stipulated by the Law ON Inspection Supervision, The Healthcare Inspector shall inform the Ministry of Health regarding his/her healthcare supervisions through the form of Work report.

A. Communicable diseases:

24. (Ref. to Q 50(a)): An update on the timeline for implementation of appropriate amendments to the Law on the protection of population against communicable diseases will be of great value.

The Law on Amendments to the Law on Protection of Population from Communicable Diseases, adopted by the Parliament of Montenegro (Official Gazette 14/10 from 17th March 2010), introduced two new diseases: Variola Vera and SARS. The Law terminologically defines epidemics of greater epidemiological significance, pandemics of communicable diseases, extraordinary situation. With a view to monitoring epidemiological situation, it is necessary for the Institute for Public Health to notify World Health Organisation, within the period of 24 hours, in accordance to International Healthcare Rulebook. For the protection of population from communicable diseases of vital importance is safe food, including safe drinking water and water for recreational purposes – (basin waters), so it was essential to incorporate them into the general communicable diseases prevention and limitation measure, and because of that it was necessary to plan and adopt special regulation on basin waters. Apart from the abovementioned amendments, with a view to harmonising it with the new Law on Sanitary Inspection it is defined, that the inspectional supervision over the application of the Law, and regulation on the basis of the Law, shall be performed by a Sanitary Inspector, and due to this fact, it was necessary to make changes, since the existing Law on Protection of Population from Communicable Diseases stipulates the inspectional supervision over the application of the Law and regulations is within the competence of a Healthcare Inspector.

Attachment: The Law on Amendments to the Law on Protection of Population from Communicable Diseases.

25. (Ref. to Q 50(b)): Contact tracing is defined as measures implemented in order to trace persons who have been exposed to a source of infectious agents, and who are potentially in danger to developing or have developed a communicable disease. How are contact tracing activities in relation with communicable diseases conducted in Montenegro?

According to the Law on the Protection of Population form Communicable Diseases (Sl. 32/2005) the measures for prevention, reduction and eradication of communicable diseases shall be taken.

If there is suspicion of incidence of a communicable disease of greater public-healthcare significance through active epidemiological and investigation and research of a person who may have or has a disease of greater public-healthcare significance, the following data shall be taken:

- regarding his/her travel outside the place of residence and contacts during the travel in a particular time period, prior to the emergence of disease,
- data on the duration of trip,
- where the person was accommodated during the travel (hotel accommodation or other),
- after the return from the travel, who s/he was with (names and surnames are taken, addresses and telephone numbers of persons who had contact with the infected person)
- were there any person who was in the proximity and with similar symptoms such as the infected person.

In addition to this, an active search and contact identification shall be performed, so the following subjects are contacted:

- air carriers, or other transport companies with a view to identifying persons who were on the same flight or travel line with the person may have or has a disease of greater public-healthcare significance,
- company where the infected or contact person works – if the person who has a disease of greater public-healthcare significance came to work prior to the occurrence of symptoms.
- other subjects, if they had contact with a person who may be or is infected by disease of greater public-healthcare significance, after return from the travel or prior to emergence of symptoms (healthcare ambulant, families visited by an infected person, etc.).

After identification of persons who were in close contact with a person who may be or is infected by disease of greater public-healthcare significance, such persons shall be placed under healthcare control during the length of incubation for a disease, or they shall be places in quarantine (if it is a quarantine disease).

During the healthcare control (decision on placing under healthcare control is issued by a state administration competent body – the Sanitary Inspection) a person may be phoned or they may be demanded to go to a chosen doctor, or healthcare institution in defined intervals (without the limitation of freedom of movement). In the case it is a quarantine disease, such persons are issued the decision of the Sanitary Inspection (limitation of freedom of movement during the maximum incubation of a disease which had led to issuance of quarantine measure and definition of compulsory health examinations).

26. (Ref. to Q 50(c)): Is there any evaluation of lessons learned from the current influenza A(H1N1) pandemic in Montenegro?

Since the WHO has not yet officially announced the end of pandemics, the final pandemics evaluation, from which particular lessons were learned, is still not conducted. It will be done after the WHO officially announces the end of pandemics. However, through the performed activities, it is possible to give certain remarks primarily related to the usefulness of conducted preparations for pandemics which Montenegro conducted in accordance to the WHO and ECDC recommendations. International exchange of data regarding the number of infected, their treatment, manner of disease spreading, disease characteristics and epidemics control in general were very useful measures. Timely dissemination of information vas relatively good, and it was of vital importance in the preparation and implementation of appropriate counter-pandemics measures.

At the same time, we can state that preliminary conclusions on the pandemics point at insufficient human resources competency i.e. readiness in the sense of reactions to the spread of unconfirmed information (related to the safety of anti-pandemics vaccines, non-existence of pandemics) through the internet, origination from different countries (even form EU). Mentioned half-truths were then transferred and published by some local electronic and print media, which confused citizens regardless of official confutes of public healthcare authorities. Furthermore, insufficient level of healthcare workers vaccinated in the EU countries, caused low level of Montenegrin healthcare workers who were vaccinated, which in turn led to even lower level of risky categories of population that were vaccinated. Mentioned consequences, make us believe, that apart from professionally well-prepared anti-pandemics measure and very real plans for the implementation of an appropriate vaccination campaigns, it is necessary to significantly better plan and provide funds and human resources for the definition of strategy for appropriate information dissemination to the general public. Apart from that, the necessary condition for successful and correct information dissemination to the public is the provision of strong cooperation between countries which would be coordinated by the WHO and ECDC.

27. Could a copy of the Law on Sanitary Inspection, due in 2009, be provided in English translation (if available)?

The Law on Sanitary Inspection is forwarded to the Ministry for European Integration.

28. (Ref. to Q 50(d)): The objectives of the Annual Programme of compulsory immunisations in Montenegro identified Influenza among the required immunisations. What was the coverage of seasonal Influenza vaccination in 2008?

The number of people (target population), older than 65, who were vaccinated against seasonal Influenza during the 2008/09 season, was about 32%.

B. Cancer screening:

29. Does Montenegro plan to implement Council Recommendation of 2 December 2003 on cancer screening? Is there a timeline for the establishment of three cancer screening programmes recommended in this document?

In Montenegro, as in all European countries, cancer represents the leading mortality cause. Out of the total number of deceased, about 17% of all deaths during a year were caused by cancer. Concerning high incidence of cancer, and a large number of people who report to a doctor during a late stadium of cancer and high mortality caused by malign diseases, Montenegro plans to implement organised screening programmes for breast cancer, colon cancer and cervical cancer, which are in accordance to the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC).

Two and a half years ago, we started a pilot project of breast cancer early detection, for women between 50 and 69, with the screening interval of 2 years. The turnout of women for screening was 80%, and final evaluation of the programme is expected by the end of March 2010. The breast cancer screening pilot project now includes women between 40 and 50. In the second quarter of 2010, the Ministry of Health will recommend to the Government of Montenegro the Draft National Project for breast cancer early detection, for women between 40 and 69 with screening interval of 2 years.

Additionally, in March 2010 we started a pilot project of colon cancer early detection which included population between 50 and 74 (men and women). Experiences of the mentioned pilot project will be the basis for the adoption of the National Screening Programme for colon cancer.

Deadline for the establishment of the National Screening Programme for breast cancer is 2010, for colon cancer is 2010, and for cervical cancer is 2011.

30. How does Montenegro envisage implementing the national population-based screening programme for breast and for cervical cancer, taking into account the European Guideline for quality assurance in breast cancer screening and diagnosis and European Guidelines for quality assurance in cervical cancer screening?

In the documents of the National Programmes for breast cancer, colon cancer and cervical cancer, which are under construction, Montenegro explicitly emphasises the need for quality provision in all phases of screening programme implementation. During social mobilisation (which is necessary in

order to achieve appropriate turnout of population for the suggested programmes), together with a written announcement, each invited person will be informed on manners of examinations and implementation of planned procedures, especially emphasising potential benefits and risks.

Early cancer detection programme significantly improves health of the population in relation to cost-benefit, only if it is well-planned, if it includes the whole of target population and if the work organisation quality is good at all levels. Screening programme can be successful only if, apart from activities targeting early detection, we have appropriate diagnostics, treatment and better life quality of the ill people. Organisation of programme for early detection is a multidisciplinary activity, and the quality of the whole of procedure (calling, diagnosing, determining of suspicious lesions, therapies, and monitoring) are necessary to provide prior to the start of the programme. Even the most professional and controlled screening programme cannot succeed if it lacks political and financial support.

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31. (Ref. to Q 54): Please provide a copy of the Strategy for Prevention and Control of Chronic Non-Communicable Diseases by 2020 and the Action Plan for the period 2009 – 2013.

The required documents are given in Annexes of Chapter 28.

Annex

1. Decree On Joint Inspection Supervision

Official Gazette of the Republic of Montenegro 48/2003 of 20 August 2003

On the basis of Article 67, paragraph 3 of the Law on Inspection Supervision (Official Gazette of the Republic of Montenegro, No. 39/03), the Government of the Republic of Montenegro, at the meeting held on 24 July 2003, adopted the

DECREE ON JOINT INSPECTION SUPERVISION

The Decree is published in the Official Gazette of the Republic of Montenegro, No. 48/2003 from 20 August 2003

Article 1

Ministries and other administration bodies (hereinafter referred to as: the inspection body) shall perform the joint inspection supervision in the manner determined by this Decree.

Article 2

Joint inspection supervision shall be performed on the basis of order of the Government of the Republic of Montenegro (hereinafter referred to as: the Government), and/or working body of the Government or on the basis of the agreement of heads of two or more inspection bodies.

Article 3

Order or agreement on joint performance of inspection supervision shall especially contain:

- Activities and tasks that should be performed, with approximate deadline for their performance;
- Inspection bodies that shall perform supervision;
- First and last name of the chief inspector and/or inspector who prepares the joint inspection supervision programme and manages the performance of supervision (hereinafter referred to as: supervision manager).

Article 4

The joint inspection supervision programme shall especially determine the following:

- Subject of supervision;
- Number of inspectors and composition of teams of inspectors;
- Time for supervision performance;
- Necessary technical and other means for joint supervision; and
- Other issues important for joint supervision.

Article 5

Supervision manager shall be obliged to submit to the head of the inspection body a proposal for determining liability of the inspector who in performance of joint inspection supervision refuses his order that is within the limits of laws and other regulations governing the acts of inspectors in certain administrative area.

Decree on Joint Inspection Supervision Page 1

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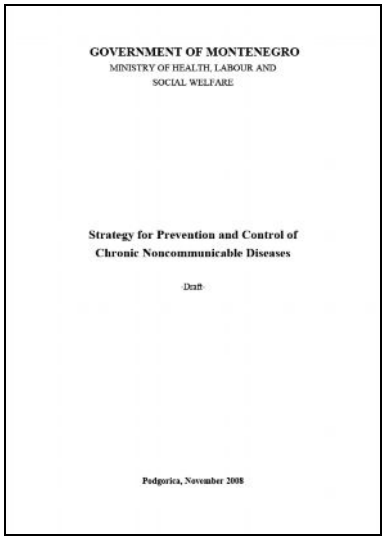
2. Strategy for Prevention and Control of Chronic Noncommunicable Diseases



GOVERNMENT OF MONTENEGRO

MINISTRY OF HEALTH, LABOUR AND SOCIAL WELFARE

Strategy for Prevention and Control of Chronic Noncommunicable Diseases

Draft

Podgorica, November 2008

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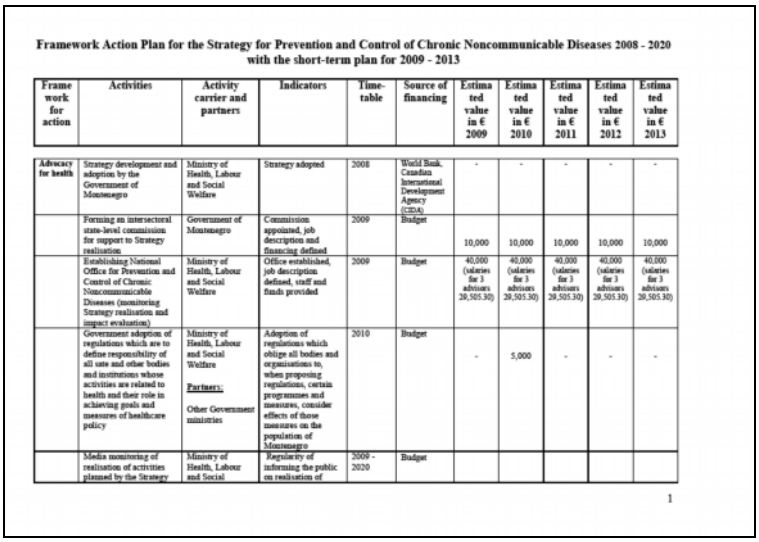
3. Framework Action Plan for the Strategy for Prevention and Control of Chronic Noncommunicable Diseases 2008 – 2020 with the short-term plan for 2009 - 2013



Framework Action Plan for the Strategy for Prevention and Control of Chronic Noncommunicable Diseases 2008 - 2020 with the short-term plan for 2009 - 2013

Frame work for action	Activities	Activity carrier and partners	Indicators	Time-table	Source of financing	Estimated value in € 2009	Estimated value in € 2010	Estimated value in € 2011	Estimated value in € 2012	Estimated value in € 2013
Advocacy for health	Strategy development and adoption by the Government of Montenegro	Ministry of Health, Labour and Social Welfare	Strategy adopted	2008	World Bank, Canadian International Development Agency (CIDA)	-	-	-	-	-
	Forming an intersectoral state-level commission for support to Strategy realisation	Government of Montenegro	Commission appointed, job description and financing defined	2009	Budget	10,000	10,000	10,000	10,000	10,000
	Establishing National Office for Prevention and Control of Chronic Noncommunicable Diseases (monitoring Strategy realisation and impact evaluation)	Ministry of Health, Labour and Social Welfare	Office established, job description defined, staff and funds provided	2009	Budget	40,000 (salaries for 3 advisors 29,505.30)	40,000 (salaries for 3 advisors 29,505.30)	40,000 (salaries for 3 advisors 29,505.30)	40,000 (salaries for 3 advisors 29,505.30)	40,000 (salaries for 3 advisors 29,505.30)
	Government adoption of regulations which are to define responsibility of all state and other bodies and institutions whose activities are related to health and their role in achieving goals and measures of healthcare policy	Ministry of Health, Labour and Social Welfare **Partners:** Other Government ministries	Adoption of regulations which oblige all bodies and organisations to, when proposing regulations, certain programmes and measures, consider effects of those measures on the population of Montenegro	2010	Budget	-	5,000	-	-	-
	Media monitoring of realisation of activities planned by the Strategy	Ministry of Health, Labour and Social	Regularity of informing the public on realisation of	2009 - 2020	Budget					

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4. The Law On Control Of Manufacture And Placing On The Market Of Substances Used In The Manufacture Of Narcotic Drugs And Psychotropic Substances

PROPOSAL FOR A LAW

THE LAW ON CONTROL OF MANUFACTURE AND PLACING ON THE MARKET OF SUBSTANCES USED IN THE MANUFACTURE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

I BASIC PROVISIONS

Article 1

This law shall regulate monitoring and control of manufacturing and placing on the market of substances used in the manufacture of narcotic drugs and psychotropic substances (hereinafter referred to as "precursors") in order to discourage their diversion or use for illicit purposes, as well as to protect people's lives and health and environment from harmful effects of precursors.

Article 2

For the purpose of this Law, the following terms shall have the following meaning:

- precursor means any substance listed in the List of precursors, including also mixture of substances or natural products containing a precursor, and which can be used in the illicit manufacture of narcotic drugs and psychotropic substances. The precursors do not include pharmaceuticals and other preparations containing precursors that are compounded in the way that they can not be easily used or extracted by readily applicable or economically viable means;
- manufacture of precursors means preparation, processing, mining, filtration or any other activity, which may manufacture or contribute to the manufacture of narcotic drugs, psychotropic substances or their preparations;
- trade in precursors means any import, export, transit, transport, storage, delivery, purchase or brokering during the purchase or sale of precursors, as well as any operation with precursors, performed by a legal person whether in return for payment or free of charge;
- transit of precursors means the transport of precursors through the territory of Montenegro, without transhipment, unloading or replacement of consignment from the point of entry to the exit from the Montenegrin territory;
- transport of precursors means the transfer of precursors from one place to another in Montenegro, without transhipment, unloading or replacement of consignment up to the place of ultimate destination in the transport of precursors in Montenegro, performed by the carrier;
- ultimate consignee means any natural or legal person to whom the precursors are delivered in the state, which serves as the place of ultimate destination;
- importer means any natural or legal person chiefly responsible for the import activities of precursors and who lodges the customs declaration or on whose behalf the customs declaration is lodged;
- exporter means any legal entity chiefly responsible for the export activities of precursors, and who lodges the customs declaration or on whose behalf the customs declaration is lodged;
- International Narcotics Control Board (INCB) is an international committee in charge of narcotics control.

Proposal for a Law 1

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5. REPORT On the Work of the Market Inspectorate for 2009

MINISTRY OF ECONOMY
Market Inspectorate

REPORT
On the Work of the Market Inspectorate for 2009

Podgorica, January 2010

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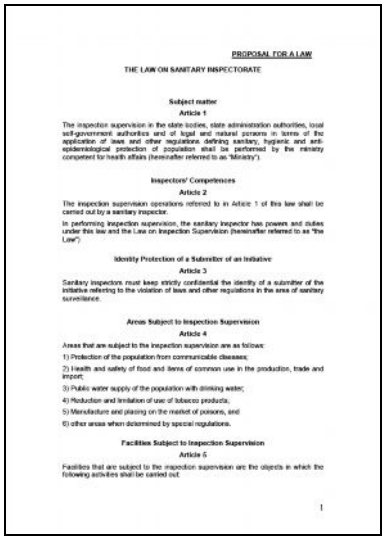
6. The Law On Sanitary Inspectorate



PROPOSAL FOR A LAW

THE LAW ON SANITARY INSPECTORATE

Subject matter

Article 1

The inspection supervision in the state bodies, state administration authorities, local self-government authorities and of legal and natural persons in terms of the application of laws and other regulations defining sanitary, hygienic and anti-epidemiological protection of population shall be performed by the ministry competent for health affairs (hereinafter referred to as "Ministry").

Inspectors' Competences

Article 2

The inspection supervision operations referred to in Article 1 of this law shall be carried out by a sanitary inspector.

In performing inspection supervision, the sanitary inspector has powers and duties under this law and the Law on Inspection Supervision (hereinafter referred to as "the Law").

Identity Protection of a Submitter of an Initiative

Article 3

Sanitary inspectors must keep strictly confidential the identity of a submitter of the initiative referring to the violation of laws and other regulations in the area of sanitary surveillance.

Areas Subject to Inspection Supervision

Article 4

Areas that are subject to the inspection supervision are as follows:

1) Protection of the population from communicable diseases;

2) Health and safety of food and items of common use in the production, trade and import;

3) Public water supply of the population with drinking water;

4) Reduction and limitation of use of tobacco products;

5) Manufacture and placing on the market of poisons, and

6) other areas when determined by special regulations.

Facilities Subject to Inspection Supervision

Article 5

Facilities that are subject to the inspection supervision are the objects in which the following activities shall be carried out:

1

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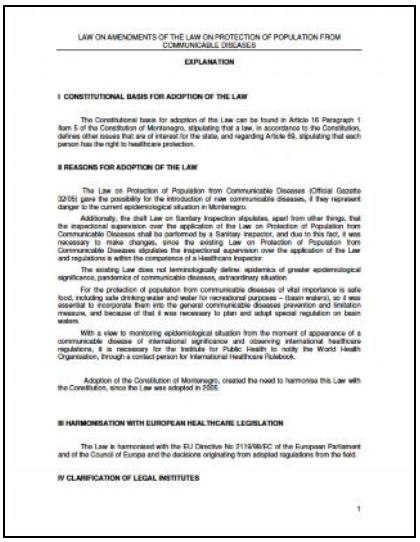
7. The Law on Protection of Population from Communicable Diseases



LAW ON AMENDMENTS OF THE LAW ON PROTECTION OF POPULATION FROM COMMUNICABLE DISEASES

EXPLANATION

I CONSTITUTIONAL BASIS FOR ADOPTION OF THE LAW

The Constitutional basis for adoption of the Law can be found in Article 16 Paragraph 1 item 5 of the Constitution of Montenegro, stipulating that a law, in accordance to the Constitution, defines other issues that are of interest for the state, and regarding Article 69, stipulating that each person has the right to healthcare protection.

II REASONS FOR ADOPTION OF THE LAW

The Law on Protection of Population from Communicable Diseases (Official Gazette 32/05) gave the possibility for the introduction of new communicable diseases, if they represent danger to the current epidemiological situation in Montenegro.

Additionally, the draft Law on Sanitary Inspection stipulates, apart from other things, that the inspectional supervision over the application of the Law on Protection of Population from Communicable Diseases shall be performed by a Sanitary Inspector, and due to this fact, it was necessary to make changes, since the existing Law on Protection of Population from Communicable Diseases stipulates the inspectional supervision over the application of the Law and regulations is within the competence of a Healthcare Inspector.

The existing Law does not terminologically define: epidemics of greater epidemiological significance, pandemics of communicable diseases, extraordinary situation.

For the protection of population from communicable diseases of vital importance is safe food, including safe drinking water and water for recreational purposes – (basin waters), so it was essential to incorporate them into the general communicable diseases prevention and limitation measure, and because of that it was necessary to plan and adopt special regulation on basin waters.

With a view to monitoring epidemiological situation from the moment of appearance of a communicable disease of international significance and observing international healthcare regulations, it is necessary for the Institute for Public Health to notify the World Health Organisation, through a contact person for International Healthcare Rulebook.

Adoption of the Constitution of Montenegro, created the need to harmonise this Law with the Constitution, since the Law was adopted in 2005.

III HARMONISATION WITH EUROPEAN HEALTHCARE LEGISLATION

The Law is harmonised with the EU Directive No 2119/98/EC of the European Parliament and of the Council of Europe and the decisions originating from adopted regulations from the field.

IV CLARIFICATION OF LEGAL INSTITUTES

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8. MARKET INSPECTION WORK PROGRAMME FOR 2008

The Republic of Montenegro
The Ministry of Economic Development
Market Inspection

MARKET INSPECTION WORK PROGRAMME
FOR 2008

Podgorica, March 2008

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9. Law On Inspection Supervision

Official Gazette of Montenegro 39/03 of 30 June 2003 and Official Gazette of Montenegro 76/09 of 18 November 2009

Pursuant to Article 88 paragraph 2 of the Constitution of the Republic of Montenegro, I hereby issue the

DECREE

PROMULGATING THE LAW ON INSPECTION SUPERVISION

(Official Gazette of Montenegro 39/03 of 30 June 2003, Official Gazette of Montenegro 76/09 of 18 November 2009)

I hereby promulgate the Law on Inspection Supervision, passed by the Parliament of the Republic of Montenegro at the second sitting of the first ordinary session in 2003 on 25 June 2003.

No 01-3312

Podgorica, 26 June 2003

The President of the Republic of Montenegro

Filip Vujanovic

LAW

ON INSPECTION SUPERVISION

I GENERAL PROVISIONS

Contents of the Law

Article 1

This Law shall govern principles of inspection supervision, the manner and procedure for its conduct, obligations and authorizations of inspectors and other issues important for the conduct of inspection supervision.

Law enforcement

Article 2

Pursuant to this Law and other regulation, Ministries and administration bodies (hereinafter referred to as: "inspection body") shall conduct inspection supervision.

Exceptionally, legal persons can conduct the inspection supervision in accordance with this Law and other regulations when these tasks are passed or entrusted to them.

The provisions of this Law shall be enforced to all administrative areas, unless a separate law exempts the enforcement of this Law.

Local self-government bodies shall apply the provisions of this Law when conducting inspection supervision in accordance with the Law and other regulations.

Concept of inspection supervision

Article 3

Inspection supervision shall be conducted in the areas governed by the law. Those areas include, as follows: physical persons, non-governmental organizations, business organizations and

Law on Inspection supervision 1

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